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(71) Applicant: PERCUSURGE, INC. [US/US]; 540 Oakmead Parkway, Sunnyvale, CA 94085 (US).

(72) Inventors: MCGILL, Scott, A.; 129 Hillview Avenue, Redwood City, CA 94062 (US). BAGAOISAN, Celso, J.; 4441 Pomponi Street, Union City, CA 94587 (US). PATEL, Mukund, R.; 427 Ridgefarm Drive, San Jose, CA 95123 (US). ERRAZO, Ariene, L.; 953 E. Duane Avenue, Sunnyvale, CA 94085 (US). NOOL, Jeffrey, A.; 460 Coyote Creek Circle, San Jose, CA 95716 (US). ZADNO-AZIZI, Gholam-Reza; 8213 Del Monte Avenue, Newark, CA 94560 (US).

(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson and Bear, LLP, 16th Floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

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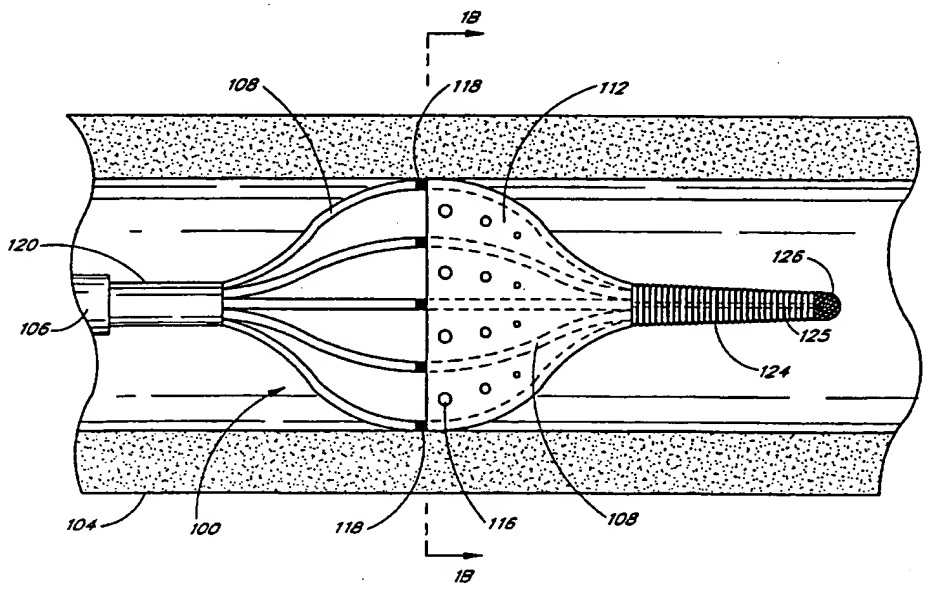
(54) Title: VASCULAR FILTERS WITH RADIOPAQUE MARKINGS



(57) Abstract: Vascular filters are disclosed which have radiopaque markings that indicate the extent to which the filter has expanded. The markings thus provide an indication to the user as to whether the filter has been properly deployed in the vessel. In preferred embodiments, the deployed filter acts as a perfusion-filter to allow for the perfusion of blood while simultaneously capturing emboli which may be generated as a result of a vascular procedure such as angioplasty. A membrane with holes therein may be used for the purpose of allowing the perfusion of blood while entraining emboli and other particulates.

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VASCULAR FILTERS WITH RADIOPAQUE MARKINGS

Background of the Invention

Field of the Invention

The invention relates generally to the field of intravascular devices for filtering emboli from blood.

Description of the Related Art

Although attempts have been made to treat occlusions in the carotid arteries leading to the brain, such arteries have been very difficult to treat because of the possibility of dislodging plaque which can then enter various arterial vessels of the brain and cause permanent brain damage. Attempts to treat such occlusions with balloon angioplasty have been limited because of such dangers. In surgical treatments, such as endarterectomy, the carotid artery is slit and plaque is removed from the vessel in the slit area. Such surgical procedures, however, also entail substantial risk.

In other procedures, such as in angioplasty and in the treatment of peripheral arteries and veins, there is the possibility that the delivery of the guide wires and catheters used in such procedures may dislodge plaque. When emboli or other particulates flow downstream to occlude blood flow in smaller vessels, they can cause serious damage, such as stroke. Thus, embolization and migration of micro-emboli downstream to an end organ is a major concern of cardiologists during catheterizations.

Various vascular filters have been proposed which would contain emboli produced as a result of intravascular procedures. However, the proper deployment of such filters remains problematic. For example, if a filter expands too far, damage to the vessel can result. Further, care must be taken when performing intravascular procedures that any interruption in the blood flow is temporary and minimal.

Thus, there remains a need for new and improved apparatuses and methods which make possible the treatment of occluded vessels without endangering the patient.

Summary of the Invention

In one embodiment of the present invention, there is provided an apparatus for use in a vessel which comprises a first elongate member and a second elongate member which passes through the first elongate member. The embodiment further comprises an expandable member connected to the first elongate member and the second elongate member. The expandable member is adjustable between a retracted position (in which the expandable member has a cross sectional profile that allows the expandable member to pass through the vessel as the apparatus is moved through the vessel) and a deployed position (in which the expandable member seals with the vessel and prevents the migration of emboli).

The embodiment further comprises a first radiopaque element, in which the first radiopaque element is operably coupled to one of the elongate members; and a second radiopaque element, in which the second radiopaque element is operably coupled to the other of the elongate members or the expandable member. The expandable member expands in response to relative movement of the first and second elongate members. The first and second radiopaque elements are disposed on the apparatus at locations selected so that the relative position of the first and second

radiopaque elements corresponds to a predetermined expansion state of the expandable member. In a preferred embodiment, the expandable member is expanded by retracting the second elongate member.

In one preferred embodiment, the first radiopaque element is operably coupled to the first elongate member at a location near where the first elongate member is connected to the expandable member. In a preferred embodiment, the second radiopaque element is operably coupled to the second elongate member at a point selected such that when the second radiopaque element is positioned next to the first radiopaque element, the expandable member has a predetermined radial expansion. In yet another preferred embodiment, the apparatus comprises a plurality of radiopaque elements operably coupled to the second elongate member at respective points, such that positioning each of the plurality of radiopaque elements next to the first radiopaque element corresponds to a different, predetermined radial expansion of the expandable member. The expandable member may advantageously have pores therein, the pores being small enough to capture emboli but large enough to permit the perfusion of blood.

In yet another embodiment of the present invention, there is provided an intravascular method, which comprises providing a device that includes an expandable member to which first and second elongate members are connected. The expandable member is inserted into a vessel, and the relative position of the first and second elongate members is varied to expand the expandable member. The radial expansion of the expandable member is determined by monitoring the relative position of at least two radiopaque elements disposed on the device. In a preferred embodiment, one of the radiopaque elements is secured to one of the elongate members and another of the radiopaque elements is secured to the other of the elongate members. In another embodiment, one of the radiopaque elements is secured to one of the elongate members and another of the radiopaque elements is secured to the expandable member. In a preferred embodiment, the expandable member is expanded by retracting the second elongate member. In one preferred embodiment, the relative position of the first and second elongate members is maintained when the expandable members has reached a desired state of expansion. In a preferred embodiment, the expandable member is expanded until it contacts the vessel wall. In one preferred embodiment, the second elongate member has a plurality of radiopaque members disposed thereon.

In still another preferred embodiment of the invention, there is provided an expandable device for use in a vessel. The device comprises a plurality of struts, at least one elongate member connected to the plurality of struts, and at least one position-indicating marker band fastened to at least one of the plurality of struts, in which the marker band has a slit therein. In a preferred embodiment, the device comprises first and second elongate members connected to first and second ends of the struts, respectively, such that the struts expand in response to relative movement of the first and second elongate members. In one preferred embodiment, the device includes a plurality of marker bands connected to respective struts. In a preferred embodiment, the respective positions of the marker bands are staggered along the struts so that marker bands connected to adjacent struts do not contact each other when the device is in an unexpanded state, thereby reducing the profile of the device.

In yet another embodiment of the present invention, there is provided a method of constructing an expandable device for use in a vessel, which comprises providing a plurality of struts, in which the plurality of struts

are connected to each other and can be expanded to contact the vessel. At least one marker band is provided having a slit therein. The method further includes sliding one of the struts through the slit of said at least one marker band, and securing said at least one marker band to said at least one strut. In a preferred embodiment, the method comprises providing a plurality of marker bands having respective slits therein, sliding the struts through respective ones of the marker bands, and securing the struts to the marker bands. In one preferred embodiment, securing the struts to the marker bands comprises securing the marker bands onto the struts. In a preferred embodiment, the struts are secured to the marker bands in a staggered arrangement such that marker bands of adjacent struts do not touch each other. In another embodiment, the marker bands are aligned along the center of the struts to yield a round profile that better assists in seeing the filter sealed against a wall of a blood vessel.

Brief Description of the Drawings

FIGURE 1A is a longitudinal cross sectional view of a perfusion-filter embodiment comprising a radiopaque element secured to an expandable member, in which the expandable member includes a plurality of ribbons and a porous membrane that allows perfusion of blood while containing emboli.

FIGURE 1B is a cross sectional view of the perfusion-filter embodiment of FIGURE 1A.

FIGURE 1C illustrates how bending the ribbons of the expandable member results in the vessel contacting the ribbons at the bends.

FIGURE 2A is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a braid, and in which the radiopaque element includes wires extending in the longitudinal direction.

FIGURE 2B is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a braid, and in which the radiopaque element includes wires oriented in the radial direction.

FIGURE 2C is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a filter-like mesh.

FIGURE 3A is a longitudinal cross sectional view of a perfusion-filter in which the expandable member includes a plurality of coils, and in which the radiopaque element is secured to the coils using a heat-to-shrink material.

FIGURE 3B is a radial cross sectional view of the embodiment of FIGURE 3A showing the relationship between the coils, the radiopaque element, and the heat-to-shrink material.

FIGURE 4 is a longitudinal cross sectional view of an expandable member that includes a slotted tube, with a radiopaque element that includes a layer on the slotted tube.

FIGURE 5A illustrates a dipping technique for forming a porous membrane on an expandable member.

FIGURE 5B shows the dried membrane formed on the expandable member.

FIGURE 6 is an embodiment in which an elongate flexible section, an expandable member, and a distal tip are integrally formed from a single hypotube.

FIGURE 7 shows a perfusion-filter device formed from a hypotube, with the perfusion filter being shown in the deployed configuration.

FIGURES 8A, 8B, and 8C show a perfusion-filter embodiment in various states of expansion, in which radiopaque markings on a pull wire and on another elongate member, respectively, are used to gauge the extent to which the expandable member has been expanded.

FIGURE 8D shows a cross section of the embodiment shown in FIGURE 8A.

FIGURE 9 shows a perfusion-filter embodiment in which a plurality of radiopaque markings on a pull wire and another radiopaque marking on another elongate member are used to gauge the extent to which the expandable member has been expanded.

FIGURES 10A, 10B, and 10C illustrate how a radiopaque marker band having a slit therein may be secured to a ribbon or strut.

FIGURE 11 illustrates how radiopaque markings may be staggered in a way that reduces the profile of the device.

FIGURE 12 is a partial sectional view of a shaft and filter subassembly deployed in a blood vessel, as well as a friction fit mechanism located proximal of the filter subassembly.

FIGURE 13 is a side view of a strut hypotube of the filter subassembly.

FIGURE 14 is a perspective view of the strut hypotube.

FIGURE 15 is a sectional view of the strut hypotube, taken along the line 15-15 in FIGURE 13.

FIGURE 16 is a side view of a pull wire for use in the shaft and filter subassembly.

FIGURES 17 and 18 are partial cross-sectional views of a kink protection system for the pull wire, reflecting system conditions when the filter subassembly is in the contracted and expanded configurations, respectively.

FIGURES 19A-19C show an adapter for use with the shaft and filter subassembly of FIGURE 12.

FIGURE 20 illustrates another embodiment of an adapter for use with the shaft and filter subassembly of FIGURE 11.

Detailed Description of the Preferred Embodiments

One embodiment of the invention is illustrated in FIGURE 1A, in which an expandable member 100 is shown in its deployed, expanded configuration within a vessel 104 such as a blood vessel. In its deployed configuration, the expandable member 100 extends throughout the vessel 104 in the radial direction. If the expandable member 100 is self-expanding, it may be deployed by retracting a sheath 106 which surrounds the expandable member, thereby allowing the expandable member to expand. On the other hand, if the expandable member 100 is not self-expanding, then a pull wire (not shown in FIGURE 1A) may be used to deploy the expandable member 100. (In this case, the pull wire could be secured to the distal end of the expandable member 100, pass through the expandable member, and exit the expandable member at its proximal end. One such pull wire arrangement is shown and discussed below in connection with FIGURES 6 and 7.) The expandable members disclosed herein are preferably non-inflatable, mechanical devices and may be designed to be either self-expanding or non-self-expanding, so that they can be deployed using either a sheath or a pull wire, respectively. An expandable member which is non-self-expanding tends towards its relaxed, undeployed position in the absence of an external force, such as the tension from a pull wire. A

self-expanding expandable member, on the other hand, has the tendency to remain in the deployed position unless acted upon by an external force, such as that provided by a sheath.

The expandable member 100 includes a plurality of ribbons 108 as well as a membrane 112 that covers the ribbons at their distal ends. The ribbons 108 may advantageously be formed from Ni-Ti, stainless steel, or elgiloy, and have a length between 6 mm and 30 mm, and more preferably between 15 and 25 mm. The cross section of the ribbons 108 may advantageously be 0.003-0.020" in one dimension by 0.009-0.040" in the other. The number of ribbons 108 is preferably between 6 and 8, although more or fewer ribbons may be used.

The membrane 112 may advantageously include a plurality of holes 116, whose size is chosen such that blood may pass through the holes as blood travels through the vessel 104 in a distal direction, whereas emboli in the blood are too large to pass through the holes and are thereby contained. The emboli are captured by that surface of the membrane 112 facing the blood as blood flows in a proximal to distal direction, i.e., the proximally facing surface. The membrane 112 as well as the other membranes disclosed herein may be PET or an elastomeric or plastic material having holes between 20 and 300 microns in diameter, and more preferably between 50 and 100 microns in diameter. (Alternatively, for some applications, it may be preferable to use non-porous membranes.) The expandable member 100 and the other expandable members disclosed herein advantageously make a seal with the vessel 104 so that emboli cannot pass distal of the expandable member 100. To this end, the radial expansion of the ribbons disclosed herein may be facilitated by advantageously imparting an initial curvature to the ribbons through heat setting.

Thus, the expandable members herein act as perfusion-filter devices which may be advantageously used in conjunction with a therapy procedure that generates emboli (such as angioplasty or another vascular procedure), i.e., the expandable members allow for the perfusion of blood while simultaneously filtering or capturing emboli and other particulates. For example, a perfusion-filter device may be positioned distal to a segment of a vessel to be treated, and then deployed. The expandable member is advantageously adjustable between a retracted position and a deployed position, in which the cross section of the expandable member in its retracted position permits the device to pass through and be positioned within the vessel, whereas the cross sectional profile of the expandable member in its deployed position substantially matches that of the cross sectional profile of the vessel, permitting the vessel to be sealed. A therapy catheter may be deployed near or at the site to be treated, and therapy may be performed on the vascular segment. The expandable member filters out or captures emboli generated during or after treatment while permitting the perfusion of blood through the expandable member during the treatment procedure. Following treatment of the vessel, the treated site may be aspirated and/or irrigated, and the expandable member (and the elongate member or catheter to which it is attached) may be retracted, and the perfusion-filter device may be removed from the patient.

Operably coupled to the expandable member 100 is a radiopaque element 118, which in FIGURE 1A is illustrated in the form of material which has been plated or crimped onto the ribbons 108 near or at their point of maximum radial extent, e.g., a gold or platinum layer having a thickness of 0.001-0.005" and a length of 0.005-0.050" may be formed on the ribbons 108. (One crimping technique is discussed below in connection with FIGURES 10A, 10B, and 10C.) Alternatively, radiopaque strips (not shown) that are approximately equal in length to the ribbons 108

may be joined to the ribbons 108 so radiopaque material extends along the entire length of the ribbons 108. The radiopaque element 118 allows the user to monitor the radial position of the expandable member 100 as the expandable member is deployed, thereby giving the user an indication as to how completely the expandable member has been deployed. The radiopaque elements herein may be gold or platinum and are preferably located adjacent the wall of the vessel 104 when the expandable member is in the deployed position. The relationship between the vessel 104, the membrane 112, the ribbons 108, and the radiopaque elements 118 secured to the ribbons is also shown in the cross sectional view of FIGURE 1B.

The expandable member 100 is advantageously connected to (e.g., bonded or crimped) or integrally formed with both an elongate member 120 and a distal tip 124. A core wire 125 (e.g., stainless steel or nitinol) may advantageously reside within the distal tips disclosed herein to enhance the structural integrity and mechanical stability of the devices. In FIGURE 1A, the core wire 125 is joined to the distal end of the tip 124 by a solder joint 126; the core wire 125 may be advantageously joined to the proximal end of the tip 124 using, for example, another solder joint (not shown). The elongate member 120 and the other elongate members disclosed herein may advantageously include a nickel-titanium alloy (such as Nitinol), elgiloy, stainless steel, braided plastic, or a composite material such as NiTi/stainless steel; they may advantageously have wall thicknesses of between 0.002 and 0.004", and have an O.D. of less than about 0.038", and more preferably an O.D. of about 0.014". The ribbons 108 are joined at their proximal end to the elongate member 120, at which point the O.D. of the device may advantageously be between about 0.018 and 0.025". The distal tip 124 (as well as the other distal tips disclosed herein) preferably includes radiopaque material and may have a length between 25 and 50 mm and an O.D. of between 0.014" and 0.030". By moving the elongate member 120 in the longitudinal direction through the vessel 104, the user can position the expandable member 100 within the vessel. The distal tip 124 facilitates proper placement of (i.e., guides) the expandable member 100 as the expandable member is positioned within the vessel 104, as is well known in the art.

The ribbons 108 may be pre-bent or weakened at various points so that the ribbons are urged to seal with the vessel 104 at those points where the ribbons have been weakened, rather than along the entire length of the ribbons, which might not result in a good seal with the vessel. This is illustrated in FIGURE 1C, which does not show radiopaque elements or a membrane for the sake of clarity. In FIGURE 1C, a plurality of ribbons 108' having respective bends therein are shown, in which the ribbons are urged towards the vessel wall 104 at the bends of the ribbons. In the embodiment of FIGURE 1C, a radiopaque member is preferably in proximity with the bends of the ribbons 108', and a membrane 112 (which may advantageously include a plurality of holes) surrounds the ribbons 108' at their distal ends.

The expandable member may alternatively include a braid, a plurality of coils, a slotted tube, or a filter-like mesh, and is preferably formed from a memory shape material such as superelastic Ni-Ti or another elastic material that is likewise bonded, crimped, or integrally formed with both an elongate member and a distal tip. In FIGURE 2A, an expandable member 200 includes a braid 208. When the braid 208 expands as illustrated in FIGURE 2A, emboli within

the vessel 104 are blocked from travelling distal of the expandable member 200. The emboli may be blocked by the braid 208 itself if the braid is formed tightly enough, or the emboli may be blocked by a membrane 212 that surrounds the braid 208 at its distal end. On the other hand, the braid 208 may be woven loosely enough to permit blood to perfuse through the braid 208. Likewise, the membrane 212 (if one is used) may advantageously contain holes 216 therein to permit the perfusion of blood while trapping emboli. Within the braid 208 there is interwoven one or more radiopaque strands 228, such that as the expandable member 200 expands, the radial extent of the expandable member can be monitored. For example, 1, 2, or 3 platinum or gold wires (0.001-0.003" thick) may be interwoven among between 8 and 32 strands of Nitinol or stainless steel. Alternatively, radiopaque ribbon may be combined with the braid 208. The overall elasticity of the device may be reduced somewhat by the presence of platinum or gold, however. As in the embodiment of FIGURE 1A, the expandable member 200 may be advantageously connected to or integrally formed with an elongate member 220, as well as a distal tip 224, with the distal tip preferably being formed from a radiopaque material.

FIGURE 2B shows a braid embodiment similar to the one of FIGURE 2A, except that the one or more radiopaque strands 228 extend throughout the expandable member 200 in the radial sense (as opposed to the longitudinal orientation of FIGURE 2A). The radiopaque element 228, and the other radiopaque elements disclosed herein, may be advantageously located near the radial extent of the expandable member to indicate the extent to which the expandable member is deployed.

Radiopaque strands 228 are also used in connection with the embodiment of FIGURE 2C, which is similar to the embodiments of FIGURES 2A and 2B, with a filter-like mesh 209 being used instead of a braid 208 to form an expandable member 201. Like the braid 208, the filter-like mesh 209 may be made of narrow strands of memory material (such as Nitinol, elgiloy, or stainless steel), although the strands of the mesh 209 are generally ordered more randomly than those in the braid 208. The mesh 209 may thus be constructed to act as a perfusion-filter without the need for a membrane, although a membrane with holes therein may be used in conjunction with the mesh 209. Either the braid 208 or the mesh 209 may be used without a membrane if the strands making up the braid or the mesh are sufficiently dense--in this sense, the braid and the mesh may be regarded as having pores.

Another perfusion mesh embodiment is illustrated in FIGURES 3A and 3B, in which an expandable member 300 includes a plurality of coils 308 which are shown in their expanded configuration within the vessel 104. A 310 wire may advantageously run through the center of each of the coils 308 to enhance the mechanical integrity of the expandable member 300. A membrane 312 covers the coils 308 distal to where the expandable member 300 seals with the vessel 104. The membrane 312 has a plurality of holes 316 therein for permitting the perfusion of blood while trapping emboli, thereby preventing them from travelling downstream of the expandable member 300. Like the other expandable members disclosed in FIGURES 1-4, the expandable member 300 advantageously makes a seal with the vessel 104. In particular, the membrane 312 contacts the wall of the vessel 104 to prevent emboli from migrating downstream. A radiopaque element 328 in the form of a cylindrical element (such as a sheath) is placed around each of the coils 308 and surrounded with a heat-to-shrink material 332. When the material 332 is heated, the material

332 collapses onto the radiopaque element 328, so that the material 332, the radiopaque element 328, and the coil 308 are held firmly together. The radiopaque elements 328 are preferably positioned along the coils 308 such that as the expandable member 300 is deployed, the radiopaque elements are located near the maximum radial extent of the coils 308, thereby allowing the user to monitor the extent to which the expandable member 300 is deployed. The expandable member 300 adjoins an elongate member 320 at one end and a distal tip 324 of radiopaque material at the other end, as in the other perfusion-filter embodiments. As an alternative to using the radiopaque elements 328, the wires 310 themselves may be radiopaque.

Another perfusion-filter embodiment is illustrated in FIGURE 4, in which an expandable member 400 includes a slotted tube portion 408. At the proximal end of the slotted tube portion 408 is an elongate member 420 (e.g., a wire or a hypotube), and at the distal end of the slotted tube portion is a distal tip 424. The elongate member 420 (and the distal tip 424) can be joined to the slotted tube portion 408 by press fitting, crimping, or joining them together.

The distal tip 424 may advantageously include a radiopaque material, and may be constructed at least in part from stainless steel, platinum, or Nitinol, or a combination thereof. As in other perfusion-filter embodiments disclosed herein, the distal end of the expandable member 400 includes a membrane 412 having holes 416 which allow for the perfusion of blood while containing emboli. Further, the expandable member 400 is joined with a radiopaque element 428, which is illustrated in FIGURE 4 as being material which has been plated onto the slotted tube portion 408, e.g., a gold or platinum layer may be formed on the slotted tube portion. However, other radiopaque elements may be used with the expandable member 400, such as one or more wires (cf. FIGURES 2A, 2B, and 2C) or material which held in place by a heat-to-shrink material (cf. FIGURE 3).

Likewise, all of the expandable members illustrated in FIGURES 1-4 and those described further below may be combined with one or more of the radiopaque elements illustrated herein, such as one or more radiopaque wires, a layer of radiopaque material (which may be a layer that has been formed by plating (see FIGURES 1 and 4), or, for example, it may be a layer within the interior of the expandable member (not shown in the figures)), or radiopaque material sandwiched between an expandable member and a heat-to-shrink material. In one example, the radiopaque element may be a coating of gold, tungsten, platinum or other material applied over the entire length of the ribbon or strut 108, preferably using electroplating. In another example, a foil of gold, tungsten, platinum or other material may be placed along the length of the struts.

Thus, the embodiments illustrated in FIGURES 1-4 should be considered exemplary, and not limiting, with respect to what kind of radiopaque element can be used with an expandable member. In addition, other techniques may be used to join a radiopaque element to an expandable member. For example, an expandable radiopaque ring (not shown) may be crimped or adhesively bonded to the expandable member. Further, the expandable member may be formed from a composite material such that the radiopaque element and the expandable member are integrally formed. So that the profile of the radiopaque element does not differ significantly from that of the expandable member, the expandable member may have a groove or undercut region (not shown) for receiving the radiopaque element, resulting

in a uniform profile of the expandable member/radiopaque element combination. The wall thickness of the ribbons 108, for example, may be reduced by etching, coining, or grinding. In all of the perfusion-filter embodiments disclosed herein, the radiopaque element on the expandable member allows the user to monitor the radial position of the expandable member as the expandable member is deployed, thereby giving the user an indication as to how completely the expandable member has been deployed.

In the embodiment illustrated in FIGURE 4, the expandable member 400 is self-expanding and deployed by retracting (pulling in the longitudinal direction) a sheath 440 which surrounds the expandable member prior to its deployment. The slotted tube portion 408 has a natural tendency to expand, and may be advantageously "shape set" for this purpose. Thus, as the sheath 440 is retracted, the expandable member expands to seal with the vessel 104, thereby preventing emboli from travelling downstream of the expandable member 400. The slotted tube portion 408 may be advantageously shape set by expanding it out (e.g., with a mandrel), and then heating it at 300-700 degrees C for between 10 seconds and 30 minutes.

The membranes 112, 212, 312, and 412 of FIGURES 1-4 may be formed, for example, by a vacuum forming process, by heat forming a plastic (such as PET), or by a dipping process. One such dipping process is outlined in FIGURES 5A and 5B, illustrated in connection with the expandable member 100 which includes the ribbons 108. As shown in FIGURE 5A, the ribbons 108 are inserted into a container 500 that holds a suitable membrane forming material 504 such as polyurethane, silicone, or a suitable plastic. If need be, a mechanical restraint such as a slug (not shown) may be placed between the ribbons 108 to keep them in an expanded position while they are being coated. The ribbons 108 may be advantageously inserted such that a roughly hemispherical fraction of the ribbons is covered. As indicated in FIGURE 5B, the membrane forming material 504 dries to form the membrane 112. Holes may be formed in the membrane 112 with a laser beam, such as an excimer laser, for example. Although no radiopaque element is shown in FIGURE 5A or 5B, the ribbons 108 may be advantageously joined with a radiopaque member prior to the dipping process.

FIGURE 6 shows an embodiment in which an expandable member 600, an elongate flexible section 604, and a distal tip 608 are integrally formed out of a single hypotube 612. Such a device 616 may be constructed by using a laser beam or EDM to drill away portions of the hypotube 612 to form the appropriate section. For example, the distal tip 608 may be formed with a laser by cutting away parts of the hypotube 612 to leave a spiral-like tip. The expandable member 600 may likewise be formed by cutting slits 620 in the hypotube to leave a section that can be radially expanded to match the contour of a vessel. Although the slits 620 are shown as being longitudinal, it will be understood that they could be at an angle with respect to the longitudinal axis, e.g., the slits 620 may form a spiral. The elongate flexible section 604 may advantageously include one or more slits 624 to increase the flexibility of the elongate member, thereby aiding the user as the device 616 is guided through a vessel, although for some applications these slits 624 may not be necessary.

Also indicated in FIGURE 6 is a pull wire 628 that runs along the length of the device 616 and is joined directly or indirectly to a distal portion of the device 616. The pull wire 628 is joined to the distal tip 608 by solder

joints 630 and 631 at the distal and proximal ends of the tip 608, respectively, so that the tip 608 maintains its orientation when the pull wire 628 is retracted. Alternatively, the pull wire 628 may be crimped to the hypotube 612, in addition to or instead of soldering, at location 631. By retracting the pull wire 628 (pulling it in the longitudinal direction), the expandable member 600 is deployed from its retracted position. The distal end portion of the pull wire 628 may advantageously include radiopaque markings 650 thereon which are discussed below in connection with FIGURE 7.

The expandable member 600 is shown in its deployed configuration in FIGURE 7, along with a membrane 632 having holes 636 therein which contain emboli while allowing the perfusion of blood. A radiopaque element 640 is also shown in FIGURE 7 which indicates the radial extent of the deployment of the expandable member 600. Perfusion of blood is possible in that blood may pass through the slits 624 or 620 and then pass out through the holes 636 in the membrane 632, whereas emboli and other particulates are advantageously captured by the holes 636.

The radiopaque markings 650 may be platinum or gold and can be secured to the pull wire 628, e.g., by crimping or adhesive bonding. The radiopaque markings 650 indicate the location of the pull wire 628 within the vessel 104. The markings 650 may be used, for example, to ascertain the length of a lesion. Also, the markings 650 may serve as landmarks to aid in the accurate positioning of a therapy catheter or device, such as a stent, delivered over the hypotube 612. Further, the markings 650 may assist the user in the proper deployment of the expandable member 600 by correlating the axial movement of the pull wire 628 with the radial expansion of the expandable member 600. (Preferred embodiments are discussed below in connection with FIGURES 8A, 8B, 8C, 8D, and 9.) This can aid the user in those situations, for example, when further retraction of the pull wire 628 does not result in any further radial movement of the radiopaque element 640. Such a circumstance might indicate to the user that the device has malfunctioned or that the user is exerting excessive force on the vessel. Pull wires having radiopaque markings may also be used with the other embodiments disclosed herein.

The elongate flexible section 604 of FIGURES 6 and 7 may advantageously be from 5 cm to 30 cm in length and may contain, for example, 2 or 3 longitudinal slits 624, or 2 or 3 helical slits (not shown), or a continuous helical slit (not shown). The slits 620 in the expandable member may advantageously be between 5 mm and 20 mm in length, and the distal tip 608 may advantageously be from 2 cm to 10 cm in length. The cuts in the distal tip 608 may advantageously be from 0.002" to 0.030" wide. The last 2 cm or so of the device 616 (the distal end) may include a gold wire or ribbon (not shown) to act as a radiopaque marking for the device.

As an alternative to the pull wire arrangement illustrated in FIGURES 6 and 7, the expandable member 600 may be "shape set" so that the expandable member tends towards an expanded, deployed configuration in the absence of any applied external forces. In this case, the expandable member may be deployed using a sheath, in analogy with the embodiment of FIGURE 4. Also, in the embodiments of FIGURES 6 and 7, the distal tip may be optionally formed as a separate piece and joined to the hypotube 612. In general, the distal tips disclosed herein preferably include radiopaque material (such as platinum or gold) to aid the practitioner in positioning the device within the vessel.

FIGURES 8A, 8B, 8C, and 8D illustrate a preferred embodiment in which radiopaque markings are used in connection with the proper deployment of an expandable member 700. A first radiopaque member 118a is secured to the pull wire 628, and, as illustrated in FIGURE 8A, the radiopaque member 118a may be advantageously located at or near the center of the expandable member 700 when the expandable member is in the undeployed position. The relationship between the vessel 104, expandable member 700, and the pull wire 628 is also illustrated by the cross sectional view of FIGURE 8D. A second radiopaque member 118b is secured to the elongate member 120. When the expandable member 700 is undeployed, the first and second radiopaque markings 118a and 118b are separated by a predetermined distance.

FIGURE 8B shows that as the pull wire 628 is retracted, the distance separating the radiopaque markings 118a and 118b decreases, since the pull wire moves relative to the elongate member 120. FIGURE 8C illustrates that as the pull wire 628 is retracted further, the expandable member 700 (in particular, the membrane 112 surrounding the ribbons or struts 108) contacts the wall of the vessel 104 to make a seal, thereby preventing the migration of emboli past the expandable member 700, while holes 116 in the membrane 112 permit the perfusion of blood. The radiopaque marking 118a may be advantageously positioned at a point on the pull wire 628 which is selected such that when the radiopaque marking 118a is positioned within and aligned with the radiopaque marking 118b (FIGURE 8C), the expandable member 700 has expanded to a predetermined diameter. If this predetermined diameter is, for example, 5 mm, and the vessel 104 has a diameter of 5 mm, then the expandable member 700 will contact the wall of the vessel 104 (FIGURE 8C) when the radiopaque marking 118a is aligned with the radiopaque marking 118b. Additionally, the expansion of the expandable member 700 may be calibrated against the relative position of the proximal (and/or distal) edge of the radiopaque marking 118a and the radiopaque marking 118b. For example, when the proximal edge of the marking 118a is aligned with the distal edge of the marking 118b, the expandable member 700 may have a (predetermined) diameter of, for example, 5 mm, whereas when the distal edge of the marking 118a is aligned with the distal edge of marking 118b, the expandable member 700 may have a (predetermined) diameter of, for example, 6 mm. Thus, the distance separating the radiopaque markings 118a and 118b indicates the extent to which the expandable member 700 has been expanded, and alignment of the radiopaque markings indicates that the expandable member has reached a desired state of expansion. After the expandable member 700 has been expanded to contact the vessel 104, the expandable member may be maintained in such an expanded state while a therapeutic procedure, e.g., angioplasty, is carried out within the vessel.

The distance separating the radiopaque markings 118a and 118b may be determined using fluoroscopy. In addition, the radiopaque marking 118a may advantageously have a known length significantly longer than its diameter, e.g., the marking 118a may be 1 mm long. This allows the practitioner to precisely establish during a fluoroscopy procedure how far away the marking 118a is from the marking 118b by using the marking 118a as a ruler, thereby allowing the practitioner to establish the degree to which the expandable member 700 has been expanded.

Although the preferred embodiment of FIGURES 8A, 8B, 8C, and 8D show a radiopaque marking on each of the pull wire 628 and the elongate member 120, other embodiments (not shown) may include one or more radiopaque

markings on one or more of the ribbons 108 of the expandable member 700 (rather than a radiopaque marking on the elongate member 120) and one or more radiopaque marking on the pull wire 628.

Another embodiment is illustrated in FIGURE 9, in which a plurality of radiopaque markings 118c, 118d, 118e are disposed along the pull wire 628. As the pull wire 628 is retracted, each of the radiopaque markings 118c, 118d, 118e, in turn, is aligned with the radiopaque marking 118b as it passes through the interior of the radiopaque marking 118b. By monitoring the relative position of the radiopaque marking 118b with respect to the markings 118c, 118d, 118e on the pull wire 628, the practitioner is provided with an indication of the extent to which the expandable member 700 has been expanded. The respective positions of the markings 118c, 118d, 118e on the pull wire 628 are preferably selected so that alignment of the markings 118c, 118d, 118e with the marking 118b corresponds to predetermined states of expansion (i.e., predetermined diameters) of the expandable member 700.

One preferred apparatus which employs radiopaque elements and a method of constructing such an apparatus is described with respect to FIGURES 10A, 10B, and 10C. FIGURE 10A shows a radiopaque marking band 800 having a slit 804 therein. The marker band 800 may be constructed of gold, tantalum, tungsten, or a platinum-iridium alloy, for example, and advantageously has a thickness between about 0.0015 and 0.002 inches. The outside diameter of the marker band 800 in FIGURE 10A may advantageously be between about 0.007 and about 0.009 inches, and the slit may form a gap of about 0.003 to 0.004 inches. As shown in FIGURE 10B, the slit 804 in the marker band 800 allows the marker band to be slipped over a ribbon 108 or strut. At this point, the marker band 800 may be crimped down over the ribbon 108 (FIGURE 10C), e.g., by using pliers or the like. One advantage to this method of construction is that the resulting ribbon 108/marker band 800 combination has a low profile. Another advantage is that this method lends itself to ease of manufacturing. Further, this method of securing marker bands 800 to ribbons 108 can be readily applied to devices like that shown in FIGURE 7, in which the ribbons are preferably formed with a laser that cuts the slits 620 in the hypotube 612. In this case, the marker bands 800 are secured to ribbons which are already connected to each other to form an expandable member, and the expandable member is connected to at least one elongate member.

This method may also be used to form devices such as those shown in FIGURE 1A, for example, and may likewise be used to construct an expandable member in which the radiopaque members are staggered with respect to each other, such that they do not contact each other when the expandable member is in a contracted position. This is illustrated with respect to FIGURE 11 which shows an expandable member 900. In this embodiment, a plurality of radiopaque members 118f, 118g, 118h, 118i (which instead of the marker bands 800 may include radiopaque material in another of the forms discussed herein, e.g., plated layers, ribbons) are secured to respective ribbons 108. The radiopaque members 118f, 118g, 118h, 118i are staggered with respect to each other, so that the profile of the expandable member 900 is reduced. The result is a compact arrangement which nevertheless permits the practitioner to monitor the extent to which the expandable member 900 is expanded.

It will be appreciated that the embodiments described above may be incorporated into any number of occlusion systems. FIGURES 12-20 illustrate one embodiment of an occlusion that may incorporate the aspects of the present invention discussed above.

FIGURE 12 illustrates a preferred embodiment of a filter device 1010 comprising a shaft 1012, a filter subassembly 1014, and a guide tip 1016. An adapter 118 (see FIGURES 19A-20) may be operably connected to the filter device to expand the filter. Further details of each of these components are described below.

In employing the device 1010, the filter subassembly 1014 is delivered on the shaft 1012 to a location in a blood vessel 1018 distal of an occlusion 1020. Through the use of the adapter 1118, the filter subassembly 1014 is expanded to occlude the vessel distal of the occlusion. Various therapy and other catheters can be delivered and exchanged over the shaft 1012 to perform treatment on the occlusion 1018. Because the filter subassembly 1014 remains expanded distal of the occlusion 1018, any particles broken off by treating the occlusion 1020 are trapped within the filter subassembly. These particles may then be removed by contracting the filter subassembly 1014 so as to contain the particles and withdrawing the device 1010 from the vessel. As an alternative or in addition to this method of particle removal, an aspiration catheter may be delivered over the shaft 1012 and used to aspirate some or all of the particles from the filter subassembly 1014.

Shaft

As shown in FIGURE 12, the shaft 1012 comprises an outer shaft member 1022, and a pull wire 1024 which extends through the lumen of the outer shaft member. The outer shaft member 1022 may comprise a hypotube as is known in the art. Multiple hypotubes may be coaxially disposed over the pull wire 1024. The shaft extends from a proximal end distally to the filter subassembly 1014. The shaft may be constructed to any desired length, however, it is preferable for the shaft to be between about 120 and 300 cm in length.

The size of the outer member of the shaft 1012 is suitable for insertion into the vasculature of a patient through an insertion site in the skin of the patient. It is preferable that the outer shaft member 1022, the pull wire 1024, and any other hypotube members are disposed coaxially such that each member is located within any larger diameter member and surrounds any smaller diameter member.

It is preferable that the largest diameter member of the shaft, for example outer member 1022 in FIGURE 12, has an exterior diameter of about 0.009 to 0.035 inches. It is more preferable that the largest diameter member of the shaft has an exterior diameter of about 0.012 to 0.035 inches, more preferably about 0.014 to 0.018 inches, and most preferably about 0.0142 inches. The wall thickness of the largest diameter hollow member of the shaft is preferably about 0.001 to 0.008 inches; i.e. the diameter of the lumen of the largest hollow member of the shaft is preferably from about 0.002 to 0.016 inches less than the outer diameter of the member. Any members located within the largest diameter member are preferably sized so as to fit within the inner lumen of the larger member.

As shown in FIGURE 12, the outer member 1022 of the shaft extends distally and is connected at its distal end to the filter subassembly 1014. The pull wire 1024 is the most centrally disposed of the shaft members. The pull wire 1024 is preferably a solid, i.e. non-tubular member around which the outer member 1022 is disposed. The pull

wire 1024 preferably extends inside the outer member 1022, through the filter subassembly 1014, and into the guide tip 1016. Alternatively, the pull wire 1024 may have two or more distinct segments, such as a proximal segment which extends to and terminates at the distal end of the strut hypotube 1030 and a distal segment which extends from that point to the distal end of the guide tip 1016.

The shaft members 1022, 1024 are preferably formed from a material which is sufficiently strong to support the shaft 1012 itself as well as the filter subassembly 1014 at the distal end under the tension, compression, and torsion experienced when inserting, operating, and removing the device from the vasculature of a patient. The material is preferably also sufficiently flexible and elastic that it does not develop permanent deformation while being threaded through the curved path necessary to reach the treatment site from the insertion point. In a preferred embodiment, the shaft 1012 has a friction-reducing outer coating of TEFLON®.

In order to satisfy these requirements, it is preferable to use a metallic tube or wire to form the shaft members 1022, 1024, although a braided or non-braided polymer tube may also provide the desired characteristics. More preferably, a superelastic memory alloy such as straight-annealed nitinol is used for the outer shaft member 1022; tempered stainless steel is one preferred material for the pull wire 1024. Other suitable alloys for the shaft members include nitinol-stainless steel alloys, or nitinol alloyed with vanadium, cobalt, chromium, niobium, palladium, or copper in varying amounts.

Filter Subassembly

Still referring to FIGURE 12, the filter subassembly 1014 extends from the distal end of the shaft 1012. The filter subassembly 1014 preferably comprises an expandable member which is either integrally formed or separately attached (as shown in FIGURE 12) to the distal end of the shaft 1012. The expandable member preferably includes an occlusive member or membrane 1026 and provides support for this occlusive member.

As used herein, "occlusion" or "sealing", and the like, refer to blockage of fluid flow in a vascular segment, either completely or partially. In some cases, a complete blockage of the blood vessel may not be achievable or even desirable, for instance, when blood flow must be maintained continuously to the region downstream of the occlusive device. In these cases, perfusive flow through the occluded region is desirable and a partial blockage is used. For example, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does not span the entire blood vessel. Alternatively, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does substantially span the entire blood vessel, but which contains openings or other means for flow to move through the occlusive member perfusively. In other cases, a partial blockage may not be achievable or desirable, and an occlusive member which substantially spans the cross section of the blood vessel without allowing perfusion is used. Each of these described structures makes use of "occlusion," as defined herein.

In the embodiment shown in FIGURE 12 the expandable member comprises struts 1028 which are formed in a strut hypotube 1030. The strut hypotube 1030 extends from the distal end of the outer shaft member 1022 to the proximal end of the guide tip 1016. At its proximal end the strut hypotube 1030 is soldered, crimped, and/or bonded, or otherwise affixed to the distal end of the outer shaft member 1022. In a preferred embodiment, a proximal taper

1031a, preferably formed from a flexible UV-cured adhesive, facilitates the connection of the strut hypotube 1030 to the shaft 1012. At its distal end the strut hypotube 1030 is crimped over a solder junction between the pull wire 1024 and the proximal end of the guide tip 1016. A distal taper 1031b, also preferably formed from a flexible UV-cured adhesive, may be employed as well in attaching the strut hypotube 1030 to the guide tip 1016. With the strut hypotube, pull wire and guide tip joined in this manner, a proximal movement of the pull wire with respect to the outer shaft member 1022 causes a corresponding proximal movement of the distal end of the strut hypotube, thus compressing the strut hypotube and urging the struts toward the expanded position.

The strut hypotube 1030 is preferably formed from nitinol, but may alternatively be formed from nitinol-stainless steel alloys, or nitinol alloyed with vanadium, cobalt, chromium, niobium, palladium, or copper in varying amounts. The strut hypotube preferably has an outside diameter of about 0.021 inches and an inside diameter of about 0.014 inches.

As best seen in FIGURES 13 and 14, the individual struts 1028 are preferably cut from, and thus integral to, the strut hypotube 1030. The struts 1028 may advantageously be formed by subjecting the strut hypotube 1030 to a laser-cutting process. Although the number of struts 1028 may vary, there are preferably between 4 and 10 (most preferably 8) struts. The struts 1028 should be equally radially spaced about the longitudinal centerline of the strut hypotube 1030.

It is preferred that the struts 1028 have a helical configuration, with each strut making approximately 1.0 revolution, at a substantially constant pitch, about the longitudinal centerline of the strut hypotube 1030 as it extends from its proximal to its distal end. Alternative preferred embodiments have straight slits which provide for non-spiral struts when deployed into the expanded configuration. The preferred helical configuration improves the apposition of the struts against the vessel wall when the filter subassembly is in the expanded configuration. The struts 1028 may advantageously have a constant clockwise pitch of about 0.650 inches and therefore the portion of the hypotube into which the struts are cut is about 0.650 inches in length. It is contemplated that the filter subassembly should reach a preferred maximum diameter of about 7.5 mm when expanded. As used herein, "strut" refers to any mechanical structure which extends from another structure or which is used to support a membrane or other structure of the occlusion device. Specifically, as discussed herein, the struts of the occlusion device are those portions of the device which extend from the shaft in order to adjust the profile of the device as discussed below, and which may be used to support the membrane.

FIGURE 15 depicts a cross-section of the strut hypotube 1030, taken along the line 15-15 as shown in FIGURE 13. The preferred laser-cutting process creates a gap of about 0.0018 inches in width between each pair of struts 1028. Each strut 1028 thus has a preferred cross-section that comprises an angular section of an annulus, with a smaller-radius inner surface 1028a and a broader, larger-radius outer surface 1028b. By virtue of their increase in size near the outer surface 1028b, the struts 1028 are stronger than a comparable set of struts that have a simple rectangular cross-section and are sized to fit within the same inner diameter-outer diameter "envelope."

With further reference to FIGURES 13 and 14, the strut hypotube 1030 may preferably incorporate a proximal cut 1032 and/or a distal cut 1034, to improve the flexibility of the hypotube. Each of the cuts 1032, 1034 is helical, with the proximal cut 1032 having a preferred substantially constant pitch of about 0.030 inches and the distal cut 1034 having a preferred substantially constant pitch of about 0.020 inches. The proximal cut 1032 and distal cut 1034 preferably extend along about 0.075 inches and 0.125 inches, respectively, of the hypotube 1030 (as measured along its longitudinal axis), and each has a preferred cut width of about 0.0018 inches. Preferably, an uncut "gap" of about 0.015 inches exists on the strut hypotube 1030 between the proximal cut 1032 and the proximal end of the struts 1028, and between the distal cut 1034 and the distal end of the struts. As shown in FIGURE 12, when the strut hypotube 1030 is attached to the shaft 1012 and the guide tip 1016, it is advantageous that no part of the cuts 1032, 1034 overlie any portion of the shaft or guide tip, so as not to impede the flexibility enhancement that is provided to the strut hypotube by the cuts.

In a preferred embodiment, one or more marker bands 1036 (see FIGURE 12) are attached to a corresponding number of the struts, and are advantageously located at or near the midpoint of each strut, so as to align the marker bands with the widest portion of the filter subassembly 1014 when it is in the expanded configuration. The marker bands may thus be aligned in a plane extending substantially orthogonal to the longitudinal axis of the shaft 1012. Alternatively, the marker bands 1036 may be staggered, i.e. attached in varying locations along the length of the struts 1028, in order to reduce the profile of the filter subassembly when it is in the collapsed configuration. The marker bands are advantageously configured to wrap around only three sides of each strut, leaving the outer surface 1028b (see FIGURE 15) exposed, in order to reduce the profile of the filter subassembly when it is in the expanded configuration. A proximal marker band (not shown) may be incorporated in a location proximal of the struts 1028 to mark a point on the device beyond which a catheter positioned on the shaft 1012 should not be advanced, thus preventing inadvertent collapse of, or damage to, the struts 1028. A preferred location for the proximal marker band is at the junction of the shaft 1012 and the strut hypotube 1030, underlying the proximal taper 1031a.

The marker bands 1036 are formed from a material having increased radiopacity in comparison to the rest of the filter subassembly, such as platinum, gold, or alloys thereof. In a preferred embodiment, the marker bands comprise an alloy of 80% platinum and 20% iridium.

As shown in FIGURE 12, the pull wire 1024 extends past the distal end of the outer shaft member 1022, beyond the strut hypotube 1030, and terminates in a solder joint 1035 at the distal end of the distal tip 1016. The tip 1016 distal to the struts 1028 preferably includes a radiopaque coil material, most preferably platinum, extending between the distal end of the strut hypotube and the solder joint 1035 to aid the practitioner in positioning the expandable member 1014 within the vessel 1018.

The membrane 1026 is preferably attached at its proximal end to the struts 1028, at or proximal of the struts' widest extent when in the expanded configuration. It is also preferred that the membrane 1026 is attached at its distal end to the strut hypotube at or adjacent the distal cut 1034. Between these proximal and distal points of attachment, the membrane tapers gradually to a smaller diameter but preferably tapers less sharply than the distal

portion of the struts 1028, so as to remain free from the struts, in a relatively loose or "baggy" state. When the expandable member is deployed, this "baggy" membrane creates a rather deep pocket for catching emboli as blood flows through the membrane 1026, and for containing the emboli when the expandable member is collapsed and withdrawn from the vessel 1018.

Alternatively, the membrane 1026 may be attached to the struts 1028 at one or more points, or in a continuous attachment, between the proximal and distal ends of the membrane. Many other arrangements are possible for the structure and attachment of the membrane 26 As used herein, "filter" and like terms mean any system which is capable of separating something out of a portion of the blood flow within the vascular segment, whether or not there is perfusion through the "filter". "Filtering" and similar terms refer to the act of separating anything out of a portion of the blood flow.

The membrane 1026 has a number of pores (not shown) of a suitable size to trap emboli while permitting blood to flow through, and are thus about 20-100 microns in size. Suitable nonelastomeric materials for the membrane 1026 include polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. The membrane may also be made from latex or silicone. The membrane may alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

Most preferably, the membrane 1026 is formed from polyurethane and has pores of about 100 microns in size, or a combination of pore sizes within the ranges detailed above. The pores are preferably spaced apart on the membrane with about 0.006 to 0.012 inches between the centers of adjacent pores, more preferably about 0.010 inches. It is also preferred that the proximal portion of the membrane lack pores, to facilitate bonding the membrane to the struts 1028 over the marker bands 1036. Likewise, the distal portion of the membrane may also be nonporous, providing easier attachment to the strut hypotube 1030.

Pull Wire

The outer shaft member 1022 surrounds the pull wire 1024 and is connected to the strut hypotube 1030 at its proximal end (see FIGURE 12). The pull wire 1024 is advantageously attached to distal end of the strut hypotube 1030, so that when the pull wire 1024 is retracted relative to the outer shaft member 1022, the struts 1028 are urged to expand in a radial direction. The relative position of the outer shaft member 1022 and the pull wire 1024 is varied until the vessel 1018 is occluded. The struts 1028 bow outwards toward the wall of the vessel 1018, so that the filter subassembly 1014 seals the vessel 1018 (i.e., in its deployed position, the expandable member prevents emboli from moving downstream). The radial expansion of the struts 1028 may also be facilitated by advantageously imparting an initial curvature to the struts 1028 through heat setting. The pull wire 1024 may advantageously extend

within the distal guide tip 1016 beyond the distal end of the strut hypotube 1030 and terminate in the solder joint 1035 at the distal end of the guide tip.

After the filter subassembly 1014 is deployed, the struts 1028 tend towards their collapsed, undeployed position in the absence of a restraining force (unless the filter subassembly 1014 is self-expanding, in which case the filter subassembly has a tendency to remain in the deployed position). To prevent the struts from returning to their undeployed position, the pull wire 1024 has one or more bends 1038 formed therein for contacting the inner wall of the outer shaft member 1022, thereby providing frictional forces which keep the filter subassembly 1014 in its expanded, deployed position, as shown in FIGURE 12. Specifically, the frictional force between the pull wire 1024 and the outer shaft member 1022 is sufficient to offset or compensate for the spring force provided by the struts 1028 and/or the membrane 1026, which would otherwise urge the struts towards their relaxed position. About 0.5-1 pound of pulling force may be required to expand the struts 1028. Thus, the bends 1038 of the pull wire 1024 engage the outer shaft member 1022 to form a compact device for restraining the pull wire from unwanted longitudinal motion. The bends 1038 of the pull wire 1024 may be formed, for example, by coining or by forming a spring in the pull wire. The bends 1038 thus act as a locking member which inhibits movement of the pull wire 1024, and the pull wire 1024 and the outer shaft member 1022 are frictionally secured together.

The pull wire features of the embodiment of FIGURE 12 can also be used if the filter subassembly 1014 is shape set so that it tends toward an expanded, deployed position in the absence of any applied forces, i.e. if the expandable member is self-deploying. In the case where an embodiment such as that shown in FIGURE 12 is constructed using a self-deploying filter subassembly 1014, the pull wire 1024 effectively acts as a push-wire which holds the filter subassembly in the collapsed configuration. This push-wire is held in place by the frictional engagement between the bends 1038 of the pull wire and the outer shaft member 1022.

When using such a device as shown in FIGURE 12 with an expandable member which is self-deploying, the filter subassembly 1014 is inserted into the vessel 1018 of the patient in its low profile position, with frictional forces between the pull wire 1024 and the outer shaft member 1022 holding the pull wire 1024 in the distal direction, which prevents the filter subassembly from expanding. The filter subassembly 1014 is then deployed by urging the pull wire 1024 in the proximal, axial direction (retracting the pull wire) with sufficient force to overcome the frictional forces between the pull wire 1024 and the outer shaft member 1022, thereby moving the locking member 1038 out of its locked position. In effect, by moving the pull wire proximally in this way, the "pushing" effect of the pull wire is eliminated, and the expandable member will deploy into the expanded configuration.

FIGURE 16 shows one preferred embodiment of the pull wire 1024. A preferred pull wire 1024 comprises a tempered stainless-steel wire with an anti-friction coating of TEFLON®. This pull wire 1024 has a tapered configuration, with a proximal section 1040 having a diameter of about 0.0086 inches; advantageously, this larger-diameter proximal section of the pull wire includes the bends 1038 described above. Distal of this section the pull wire tapers to a medial section 1042 having a diameter of about 0.007 inches. The pull wire shown has a diameter of about 0.0025 inches at its most distal section 1044; this diameter advantageously prevails over the most distal 3 cm

of the pull wire. A tapered transition 1046 of about 3 cm in length is interposed between the medial section and the distal section. The pull wire of FIGURE 16 has an overall length of about 212.0 cm; the proximal section (having the diameter of about 0.0086 inches) is about 17.0 cm in length. The medial section is thus about 189.0 cm in length.

Pull Wire Kink Protection

FIGURES 17 and 18 depict a kink protection system 1100 that may preferably be used to prevent the proximal portion of the pull wire 1024 from kinking when it is pushed distally against the frictional resistance of the bends 1038 and, where the filter subassembly 1014 is of the self-expanding type, against the spring force of the struts 1028. The system 1100 comprises a pre-expanded coil 1102 and a proximal hypotube 1104. The coil 1102 is connected to the proximal tip of the outer shaft member 1022 by soldering or other conventional methods and surrounds that portion of the pull wire 1024 which is immediately proximal of the outer shaft member. The proximal hypotube 1104 is crimped to the pull wire 1024 and is attached to the proximal end of the coil 1102 by soldering or other conventional methods.

FIGURE 17 shows the system 1100 when the filter subassembly is in its contracted configuration, and the coil 1102 is compressed. FIGURE 18 shows the system 1100 when the filter subassembly is in the expanded configuration. The pull wire 1024 has been pulled proximally from the outer shaft member 1022 and the coil 1102 is in its relaxed state. When the pull wire 1024 is pushed back distally into the outer shaft member 1022 (see FIGURE 17), the coil 1102 augments the column strength of the pull wire 1024 by presenting a coaxial, larger-diameter column for absorbing the compressive force that is applied to the coil-pull wire assembly. Off-axis loads are thus less likely to bend or kink the pull wire 1024 as it is pushed into the outer shaft member 1022.

Adapter

The pull wire 1024, shown in FIGURE 12, is manipulated through the use of an adapter or manifold 1118 (see FIGURES 19A-20). The adapter enables the technician to control the relative positioning of the pull wire 1024 and the outer shaft member 1022 in a simple manner. Although FIGURES 19A-20 illustrate the adapter as manipulating the pull wire 1024, it will be appreciated that in embodiments wherein a proximal hypotube is provided over the pull wire 1024, the adapter manipulates this proximal hypotube.

After delivery of the device to the desired location within the vasculature of the patient, the adapter 1118 is attached and the pull wire 1024 is manipulated through the use of the adapter 1118 so as to deploy the filter subassembly 1014 of the device. At this point, the adapter may be removed from the device so that therapy may be performed.

One type of adapter 1118 used in accordance with preferred embodiments of the filter device is shown in FIGURES 19A-19C. Without regard to whether the expandable member is of the shape set variety (self-expanding) or is undeployed when relaxed, the degree to which the expandable member is deployed can be monitored by noting the longitudinal position of the pull wire 1024. This allows the user to carefully control the extent to which the expandable member is deployed. A thumb wheel 1134 is used to control the position of the pull wire 1024 relative to the outer shaft member 1022, thereby controlling the extent to which the filter subassembly 1014 of FIGURE 12 is

expanded. As illustrated by the view of FIGURES 19B-19C, the adapter 1118 includes two halves 1136, 1138 preferably formed of medical grade polycarbonate or the like.

The two halves 1136, 1138 are attached by at least one hinge 1140, so that the halves are joined in a clam shell manner. A latch 1142 secures the two halves 1136, 1138 while the adapter 1118 is in use. The latch includes a pair of flexible, resilient latching members 1144, 1146 which are mounted within the half 1138. A space 1148 between the two latching members 1144, 1146 receives a locking pin 1150 which has a beveled head 1152. The head 1152 passes through the space 1168 and past the latching members 1144, 1146. The latching members 1144, 1146 prevent the locking pin 1180 from backing out past the latching members which would open up the adapter 1118. To open the halves 1136, 1138, the latching members 1144, 1146 are separated slightly by depressing a flexure member 1154, which pries apart the latching members slightly, thereby freeing the locking pin 1150.

The outer shaft member 1022 may be held in place by a groove (not shown) having a width selected to accept the outer shaft member 1022. Alternatively, as shown in FIGURE 19C, the outer shaft member 1022 and the pull wire 1024 may be held by clips 1156a, 1156b, 1156c, 1156d having respective slots 1158a, 1158b, 1158c, 1158d therein for receiving the outer shaft member and the pull wire. In particular, the outer shaft member 1022 and the pull wire 1024 may advantageously be configured so that the outer shaft member rests within clips 1156a, 1156b, 1156c, with the pull wire extending between the clip 1156c and the clip 1156d and extending proximal to the clip 1156d. With this arrangement, and when the adapter 1118 is in the closed position, the pull wire 1024 may be engaged and moved by a first pair of contact members such as oppositely facing pads 1160a, 1160b, while the outer shaft member 1022 is held stationary by one or more other pairs of oppositely facing pads 1160c, 1160d and 1160e, 1160f. Alternatively, the device may be designed so that the outer shaft member 1022 is moved while the pull wire 1024 remains stationary. The pads 1160a-f may advantageously include a plurality of ridges 1162 for securely contacting the pull wire 1024. The clips 1156a, 1156b, 1156c, 1156d fit within respective cavities 1164a, 1164b, 1164c, 1164d in the adapter half 1136 when the two halves 1136, 1138 are closed.

To aid the user in properly aligning the outer shaft member 1022 and the pull wire 1024 within the adapter 1118, a mark may be placed on the outer shaft member 1022. For example, an alignment mark on the outer shaft member 1022 may indicate that point on the outer shaft member 1022 which must be placed within the slot 1158a so that the outer shaft member extends within the adapter 1118 up to but not proximally beyond the clip 1156c, with the pull wire 1024 being exposed proximal to the clip 1156c. This configuration permits the pads 1160a, 1160b to retract (or advance) the pull wire 1024 into (or out of) the vessel while the outer shaft member 1022 is held securely within the pads 1160c, 1160d and 1160e, 1160f.

When the pull wire 1024 is not being advanced or retracted through the outer shaft member 1022 by the pads 1160a, 1160b, relative movement of the pull wire and the outer shaft member is advantageously prevented by frictional contact between the bends 1038 of the pull wire 1024 and an inner surface of the outer shaft member 1022 (see FIGURE 12). This permits the introduction of a therapy catheter (not shown) such as an angioplasty or stent catheter, or the exchange of a plurality of catheters, after the adapter 1118 is decoupled and removed from the outer

shaft member 1022 and the pull wire 1024. For example, once the filter subassembly 1014 is deployed, an angioplasty or stent catheter may be introduced over the outer shaft member 1022 and the pull wire 1024. After therapy is performed, an aspiration (and/or irrigation catheter) may be introduced over the outer shaft member 1022/pull wire 1024 to aspirate (and/or irrigate) away emboli entrained in the filter subassembly 1014 which were produced as a result of the therapy procedure. The adapter 1118 may then be recoupled to the outer shaft member 1022 and the pull wire 1024, followed by deactivation (retraction) of the filter subassembly. The filter subassembly 1014, the pull wire 1024, and the outer shaft member 1022 may then be removed from the vessel.

When the adapter 1118 is in the closed position, the pads 1160c, 1160d, 1160e, 1160f surround and contact the outer shaft member 1022 to prevent its motion. The pads 1160a, 1160b, on the other hand, are mounted in respective holders 1161a, 1161b which are slidable within respective recessed portions 1163a, 1163b of the adapter 1118, so that when the pads 1160a, 1160b, surround and contact the pull wire 1024, the pull wire may be retracted or advanced. Specifically, the holder 1161a (housing the pad 1160a) is mechanically coupled to and controlled by the wheel 1134, as discussed in more detail below. When the adapter 1118 is closed, the pads 1160a and 1160b are compressed together and squeeze the pull wire 24 between them. As the user rotates the wheel 1134, the pad 1160a is moved in the longitudinal direction, and the pad 1160b and the pull wire 1024 are moved along with it. Thus, by rotating the wheel 1134, the user may control the longitudinal position of the pull wire 1024 with respect to the outer shaft member 1022, and thereby control the extent to which the expandable member is radially deployed. The pads 1160a-f may be formed from C-Flex or Pebax and are preferably about 0.5-1.0" long, 0.25-0.5" wide, and 0.125-0.25" thick.

The wheel 1134 imparts motion via a cam mechanism (not shown) to the pad 1160a which moves the pull wire 1024 incrementally. The wheel 1134 may advantageously move the pull wire 24, for example, between 3 mm and 20 mm as indicated by a dial 1135 on the face of the wheel (see FIGURE 19A), thereby controlling the extent to which the expandable member is expanded by controlling the position of the pull wire. The dial 1135 acts as a gauge of the relative longitudinal position of the pull wire 1024 within the vessel, and thus as a gauge of the extent to which the expandable member has been expanded.

Another embodiment of the adapter 1118 is shown in FIGURE 20. This embodiment has the same basic configuration as that shown in FIGURES 19A-19C, i.e., a clamshell with two halves 1136, 1138 rotatably connected by at least one hinge 1140. A resilient locking clip (not shown) may be mounted in a recess 1180 formed in the upper half 1136 and extend downward therefrom. Upon closure of the adapter 1118 an inwardly-extending tongue formed on the locking clip snaps into a groove 1182 formed in the lower half 1138. The locking clip holds the adapter 1118 firmly closed by virtue of an interference fit between the tongue and the groove 1182.

In place of the thumb wheel 1134 shown in FIGURES 19A-19C, this embodiment of the adapter 1118 incorporates a knob 1184 that is rotated by the user to move the pads 1160a, 1160b and advance/retract the pull wire 1024. Like the thumb wheel 1134, the knob 1184 may incorporate appropriate markings (not shown) to indicate the extent to which the filter has been expanded or retracted by the action of the adapter 1118.

Like the adapter shown in FIGURES 19A-19C, the adapter 1118 of FIGURE 20 includes pads 1160c, 1160d, 1160e, 1160f that grip the outer shaft member and hold it stationary while the pull wire is advanced or retracted within it. Clips 1156a, 1156b, 1156c having respective slots 1158a, 1158b, 1158c receive the outer shaft member and/or pull wire and maintain it in a straight configuration for the filter deployment/retraction process. Upper and lower channel halves 1186a, 1186b coact to create, upon closure of the adapter 1118, a channel that receives and grips the outer shaft member and the pull wire, preferably immediately adjacent the pads 1160a, 1160b.

A pin member 1188 is positioned on the upper half 1136 so that the pin 1188 is depressed by the pull wire when the adapter 1118 is closed with the outer shaft member and pull wire positioned therein. The pin member is mechanically coupled to an interrupt mechanism (not shown) that prevents rotation of the knob 1182 unless the adapter 1118 is closed with the pull wire, etc. in position (and the pin member 1188 depressed by contact with the pull wire).

Strut Design

With further reference to FIGURE 12, the filter device includes a filter subassembly 14 which is located along the shaft 1012 near the distal end, and proximal of the guide tip 1016. In one embodiment the filter subassembly may be integrally formed with the outer member 1022 of the shaft 1012. The filter subassembly 1014 comprises a number of struts 1028 and an occlusive member or membrane 1026. The struts support the membrane, and provide for at least two configurations of the device, a collapsed configuration and an expanded configuration. The expanded configuration is shown.

The "collapsed" configuration refers to the lowest profile configuration of the struts. In this context, "profile" refers to the distance away from the axis of the device that is spanned. Therefore, "low profile" refers to configurations in which the device is entirely within a small distance from the axis of the device. The "collapsed configuration" is the configuration in which the struts have the lowest possible profile, that is, where they lie as close as possible to the axis of the device. Having a low profile configuration simplifies insertion and removal of the device, and strut designs which tend to reduce the profile of the occlusion device are advantageous.

In the collapsed configuration, the embodiment shown in FIGURE 12 would have the struts 1028 and the occlusive member 1026 positioned as close as possible to the longitudinal axis of the device, i.e. they would have the smallest possible cross-section. This configuration facilitates the deployment of the filter subassembly 1014 by permitting easier delivery through the blood vessel 1018 on the distal end of a catheter shaft, as well as easier retrieval of the filter subassembly 1014 at the conclusion of the procedure. By minimizing the profile of the filter subassembly, this configuration is more easily passed through the vasculature leading to the filtration site from the insertion point.

When moved from the expanded configuration, shown in FIGURE 12, into the collapsed configuration, the membrane 1026 may not lie in the same profile as it did prior to deployment into the expanded configuration. This is because the membrane is retracted strictly by the action of the struts, and excess folds of material may extend from between the struts in the collapsed configuration. This may cause the profile of the filter subassembly 1014 to be

larger after retraction than it was prior to deployment. This enlarged profile can cause the membrane 1026 to rub against the vessel walls in an undesirable manner.

In the "expanded" configuration shown in FIGURE 12, the struts 1028 and the occlusive member 1026 are positioned such that they span substantially the entire width of the blood vessel 1018 in which they are positioned. This is preferably the highest profile possible for the struts within the blood vessel. This configuration facilitates the use of the filter subassembly 1014 to trap embolic matter while permitting passage of blood through the filter subassembly. By providing a means to span substantially the entire width of the blood vessel 1018 to be filtered, the struts 1028 support the occlusive member 1026 in a configuration which forces the blood flow through the vessel to pass through the pores or openings in the filter subassembly 1014 while retaining emboli therein. This produces the desired filtering effect.

Actuation of the struts in order to adjust the device from the collapsed configuration to the expanded configuration (shown in FIGURE 12) is achieved using either a tension or a torsion mechanism. In tension based actuation, the pull wire 1024 is displaced axially within the outer shaft member 1022 in a proximal direction. In one preferred embodiment, this displacement allows the struts to expand under a built-in bias into the expanded configuration. In the embodiment shown in FIGURE 12, the displacement applies an outward biasing force to the struts. In torsion based actuation, the pull wire 1024 is rotated with respect to the outer shaft member 1022, resulting in a rotational displacement which applies an outward biasing force to the struts. In order to adjust from the expanded to the collapsed configuration, the actuation is reversed, by either pushing or rotating the pull wire in the direction opposite from that used in the deployment, reversing the force upon the struts, and returning the device to the original configuration. Additional details are disclosed in the above-referenced STRUT DESIGN FOR AN OCCLUSION DEVICE.

Membrane

As seen in FIGURE 12, the occlusive member or membrane 1026 is preferably attached to each of the struts 1028 and extends completely around the longitudinal axis of the device. Preferably, the occlusive member 1026 is attached to the outer surface of the struts 1028; however, it may be attached along the inside of the struts 1028 as well. Moreover, it will be appreciated that the filter membrane may be provided inside some of the struts and outside of others. It will also be appreciated that struts may be provided on both sides of the membrane in a sandwiched configuration, or that two membranes may sandwich a set of struts.

At its distal end the occlusive member 1026 is preferably joined to the strut hypotube 1030, or, alternatively, to the guide tip 1016. As the occlusive member 1026 can be constructed in varying lengths, its proximal end may be located between the midpoint and the proximal end of the struts 1028. Where the occlusive member 1026 extends along the entire length of the struts 1028 it may also be attached at its proximal end to the strut hypotube 1030. Thus, when the struts 1028 are radially expanded, the occlusive member 1026 will likewise expand so as to take on a cross-sectional area corresponding approximately to that of the internal dimensions of the blood vessel 1018. It is

contemplated that the occlusive member can be joined to the struts 1028 and strut hypotube 1030 by employing standard attachment methods, such as heat fusing, adhesive bonding, etc.

One preferred occlusive member 1026 is a nonelastomeric membrane with a number of pores which are approximately 20-100 microns in diameter. Suitable nonelastomeric materials include, but are not limited to: polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. This type of occlusive member may be extruded or dip molded, with the pores formed by the mold itself, or subsequently using an excimer laser or other drilling process.

One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. The membrane may also be made from latex or silicone. The occlusive member may alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

A variety of pore configurations are suitable for use with the occlusive member. First, where the membrane extends along the entire length of the struts, about 2-10 pores of about 20-200 microns diameter may be arranged longitudinally along the occlusive member to provide perfusion. Another suitable configuration for this type of occlusive member consists of several pores of about 20-200 microns in diameter on the distal half of the member, and large triangular, round, or square cutouts on the proximal half. Alternatively, the entire surface of the occlusive member may have pores of about 20-200 micron size. This configuration is also contemplated for use where the occlusive member 1026 has an open proximal end. When using this type of occlusive member, a non-permeable cover or web may be placed over the juncture of the proximal ends of the struts to the distal shaft, to prevent formation of thrombi in the narrow passages formed at this point.

The membrane may be mounted on the device so as to create a loose or "baggy" portion of the membrane between proximal and distal points of attachment to the struts and to the strut hypotube/guide tip, respectively. In other words, the membrane may have a proximal point or region of attachment to the struts, a baggy portion distal of the proximal point of attachment in which the membrane is unattached to the device, and a distal point of attachment distal of the baggy portion. On such a membrane, the distal and proximal portions that are intended for attachment to the struts, guide tip and/or strut hypotube may preferably be substantially nonporous, to permit better adhesion. In one preferred embodiment, this membrane may have about 400 to 1000 pores, more preferably about 700-800 pores.

The membrane or occlusive member may also comprise a strut-deployable balloon that incorporates perfusion tubes which permit fluid communication (but not flow of emboli) between the proximal and distal sides of the balloon. The perfusion tubes may comprise lengths of tubing which terminate (at their proximal and distal ends, respectively) at points of intersection with the proximal and distal faces of the balloon. Alternatively, perfusion may be facilitated

through the lumen of the outer shaft member via openings formed therein proximal of the balloon, and via the (porous) guide tip distal of the balloon. A valve system may be employed to regulate the flow of fluid through the lumen.

The device may also employ dual occlusive members on a single set of struts, with a proximal filter with relatively large pores and a distal filter with smaller pores. With any of the mentioned types of occlusive member, it is contemplated that an aspiration catheter may be employed to remove thrombi from the filter(s) at various points in an angioplasty or other similar procedure.

Guide Tip

As shown in FIGURE 12, located most distally upon the shaft 1012 is a guide tip 1016. The guide tip lies distal of the filter subassembly 1014 and provides a flexible leading extension which bends to follow the curvature of the blood vessels through which the device is advanced. By bending to follow the wall of the blood vessel, the guide tip 1016 leads the filter subassembly 1014 and other more proximal elements of the device in the direction of the tip so as to make the device move through the vessel without excessive impact against the walls of the blood vessels of the patient.

With further reference to FIGURE 12, in one embodiment the guide tip 1016 is formed by creating a rounded solder joint tip 1035 to the pull wire 1024 of the shaft 1012, and wrapping it in a thinner wire to produce a coil which provides a spring force between the filter subassembly 1014 and the rounded tip 1035. The wire used for the coil 1016 is preferably made of a radiopaque material. Because the pull wire 1024 is constructed of a flexible material, such as nitinol, it will bend when the rounded tip 1035 is pushed against the curving wall of a blood vessel. However, as the deflection of the tip increases, the spring force of the coil of thinner wire will urge the filter subassembly 1014 and shaft 1012 into alignment with the guide tip 1016. In this way, the entire shaft is made to follow the path of the guide tip 1016 as it advances through the blood vessels toward the treatment site.

Operation

The use of the described embodiments of the instant invention will generally be part of a process of therapy on a portion of the blood vessel of a patient. Usually, the therapy will involve treatment of some form of blockage of the blood vessel. However, those skilled in the art will recognize that the use of the described invention is appropriate in any situation where there is a possibility of embolic matter being dislodged from the vasculature of the patient, and therefore a desire to inhibit the dispersal of such embolic matter into the bloodstream of the patient.

As used herein, "method" refers to a preferred sequence used to accomplish a goal. Furthermore, the method which is described below is not limited to the exact sequence described. Other sequences of events or simultaneous performance of the described steps may be used when practicing the instant invention.

First, the device is manipulated so that the filter subassembly or subassemblies are in the collapsed position. This simplifies the insertion of the device into the blood stream of the patient. The device is then inserted through an insertion site into a blood vessel of the patient. Once inserted into the vasculature of the patient, the device is advanced distally until the distal portion of the device is located adjacent to the region of the blood vessel to be treated.

The device is positioned such that the filter subassembly lies generally downstream of the treatment site, or more generally, such that the filter subassembly lies between the treatment site and any site which is of particular susceptibility to embolic damage (e.g., the brain or coronary arteries). In this way, the filter is positioned so as to intercept any embolic matter dislodged at the treatment site, before such embolic material can reach any vulnerable area or be dispersed through the blood flow of the patient.

Once in position, the filter subassembly is actuated so that it assumes its expanded configuration, effectively occluding the blood vessel so that all blood flow must pass through at least one of the filter membranes or other occlusive members of the device.

The desired therapy is now performed upon the region of the blood vessel to be treated. This may involve placement or removal of support stents, balloon angioplasty, or any other vascular therapy that is conducted through the use of interventional techniques. In the course of such interventional treatment, additional catheters or other devices may be introduced to the treatment area by threading them over or along the shaft of the occlusive device. During the therapy, any embolic matter which is dislodged will flow into the filter and be caught by the membranes supported by the struts.

At any point during the therapy, the embolic matter may be aspirated from the filters through the use of separate aspiration catheters or through the lumen of the outer hypotubes forming the shaft of the occlusive device. Such aspiration may be repeated as often as necessary to maintain perfusive blood flow through the filter subassembly and treated region.

When the therapy is concluded, the filter subassembly is retracted into its collapsed configuration by reversing the actuation process. This will return the struts to a low profile which can then be withdrawn from the patient through the insertion site.

Although preferred embodiments of the present invention have been described herein, it will be understood by those of ordinary skill in the art that certain obvious modifications and departures from these embodiments can be made without departing from the spirit or essential characteristics of the invention.

WHAT IS CLAIMED IS:

1. An apparatus for use in a vessel, comprising:

an expandable member, said expandable member adapted to be connected to an elongate member and being adjustable into:

a retracted position in which said expandable member has a cross sectional profile that allows said expandable member to pass through the vessel as the elongate member is moved through the vessel; and

a deployed position in which said expandable member seals with the vessel to prevent the migration of emboli; and

a radiopaque element operably coupled to said expandable member to indicate the radial extent of said expandable member in the vessel during a vascular procedure.

2. The apparatus of Claim 1, wherein said expandable member has pores therein, said pores being small enough to capture emboli but large enough to permit the perfusion of blood.

3. The apparatus of Claim 2, said expandable member sealing with the vessel when said expandable member is in the deployed position, said expandable member having a porosity selected to capture emboli while allowing blood to perfuse through said expandable member.

4. The apparatus of Claim 1, further comprising an elongate member operatively coupled to said expandable member, such that said expandable member can be positioned within the vessel by moving said elongate member.

5. The apparatus of Claim 4, wherein said elongate member and said tube are integrally formed from a single hypotube.

6. The apparatus of Claim 1, wherein said expandable member includes at least one member selected from the group consisting of a braid, a plurality of coils, a ribbon-like structure, a slotted tube, and a filter-like mesh.

7. The apparatus of Claim 1, wherein said radiopaque element is adjacent the wall of the vessel when said expandable member is in the deployed position.

8. The apparatus of Claim 7, wherein said radiopaque element includes a wire.

9. The apparatus of Claim 1, wherein said expandable member includes a plurality of wires forming a braid and said radiopaque element includes a wire distributed within said expandable member.

10. The apparatus of Claim 1, wherein said radiopaque element includes material plated onto said expandable member.

11. The apparatus of Claim 1, wherein said radiopaque element includes a layer on said expandable member.

12. The apparatus of Claim 11, wherein said radiopaque element is bound to said expandable member by a heat-to-shrink material.

13. The apparatus of Claim 1, further comprising a coil tip at the distal end of said expandable member.

14. The apparatus of Claim 1, wherein said expandable member is self-expanding.

15. The apparatus of Claim 1, wherein said expandable member is deployed by moving a pull wire.

16. The apparatus of Claim 1, wherein said expandable member includes a membrane having pores therein.

17. The apparatus of Claim 16, wherein said membrane has a proximally facing surface that faces blood flowing in a proximal to distal direction, such that emboli are captured by said membrane.

18. The apparatus of Claim 1, wherein said expandable member includes a slotted hypotube.

19. The apparatus of Claim 1, wherein said expandable member includes a plurality of struts.

20. The apparatus of Claim 19, wherein said radiopaque element includes a plurality of radiopaque markers attached to said struts.

21. The apparatus of Claim 20, wherein said markers are attached to said struts such that they are staggered along said struts so that markers attached to adjacent struts do not contact each other when the device is in an unexpanded state, thereby reducing the profile of said device.

22. The apparatus of Claim 20, wherein said markers are attached to said struts such that they are aligned along a common plane.

23. The apparatus of Claim 20, wherein said markers are applied over the length of said struts.

24. The apparatus of Claim 23, wherein said markers are electroplated onto said struts.

25. The apparatus of Claim 20, wherein said markers are foils applied to said struts.

26. The apparatus of Claim 1, wherein said markers are made of a material selected from the group consisting of gold, platinum and tungsten.

27. An apparatus for use in a vessel, comprising:

a first elongate member;

a second elongate member passing through said first elongate member;

an expandable member connected to said first elongate member and said second elongate member, said expandable member being adjustable between:

a retracted position in which said expandable member has a cross sectional profile that allows said expandable member to pass through the vessel as said apparatus is moved through the vessel; and

a deployed position in which said expandable member seals with the vessel and prevents the migration of emboli;

a first radiopaque element, said first radiopaque element operably coupled to one of said elongate members; and

a second radiopaque element, said second radiopaque element operably coupled to the other of said elongate members or said expandable member;

wherein said expandable member expands in response to relative movement of said first and second elongate members, and said first and second radiopaque elements are disposed on said apparatus at locations selected so that the relative position of said first and second radiopaque elements corresponds to a predetermined expansion state of the expandable member.

28. The apparatus of Claim 27, wherein said expandable member is expanded by retracting said second elongate member.

29. The apparatus of Claim 28, wherein said first radiopaque element is operably coupled to said first elongate member at a location near where said first elongate member is connected to said expandable member.

30. The apparatus of Claim 29, wherein said second radiopaque element is operably coupled to said second elongate member at a point selected such that when said second radiopaque element is positioned next to said first radiopaque element, said expandable member has a predetermined radial expansion.

31. The apparatus of Claim 29, comprising a plurality of radiopaque elements operably coupled to said second elongate member at respective points, such that positioning each of said plurality of radiopaque elements next to said first radiopaque element corresponds to a different, predetermined radial expansion of said expandable member.

32. The apparatus of Claim 28, wherein said expandable member has pores therein, said pores being small enough to capture emboli but large enough to permit the perfusion of blood.

33. An expandable device for use in a vessel, comprising:

a plurality of struts;

at least one elongate member connected to said plurality of struts; and

at least one position-indicating marker band fastened to at least one of said plurality of struts, said marker band having a slit therein.

34. The device of Claim 33, comprising first and second elongate members connected to first and second ends of said struts, respectively, such that said struts expand in response to relative movement of said first and second elongate members.

35. The device of Claim 34, comprising a plurality of marker bands connected to respective struts.

36. The device of Claim 35, wherein the respective positions of said marker bands are staggered along said struts so that marker bands connected to adjacent struts do not contact each other when the device is in an unexpanded state, thereby reducing the profile of said device.

37. The device of Claim 35, wherein the respective positions of said marker bands are aligned on a common plane orthogonal to the longitudinal axis of the elongate member.

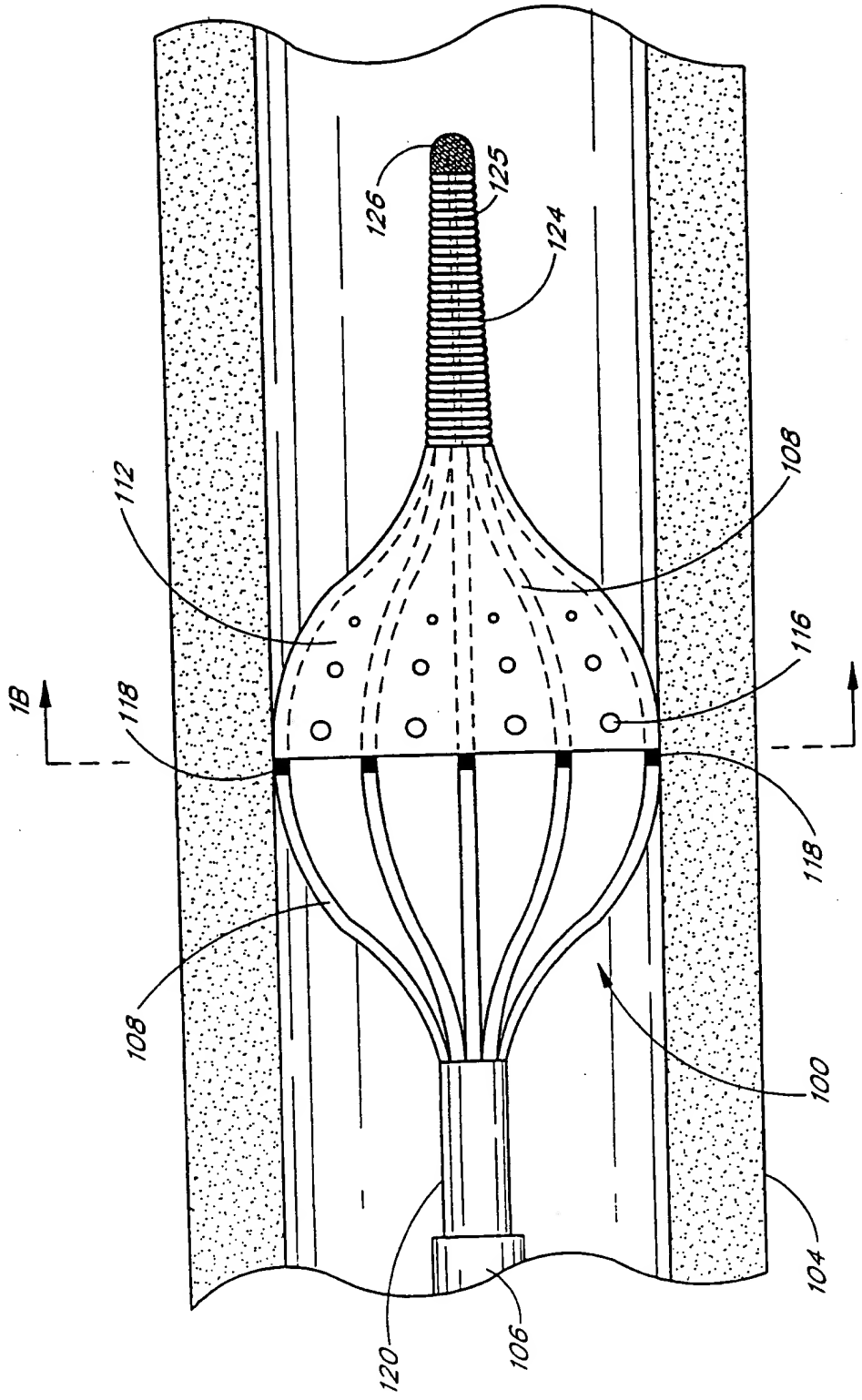

FIG. 1A

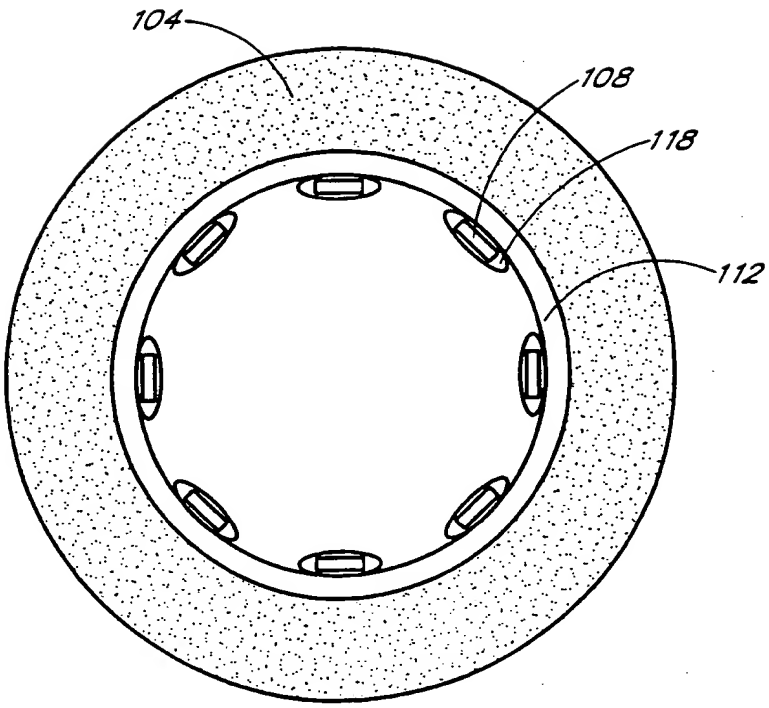

FIG. 1B

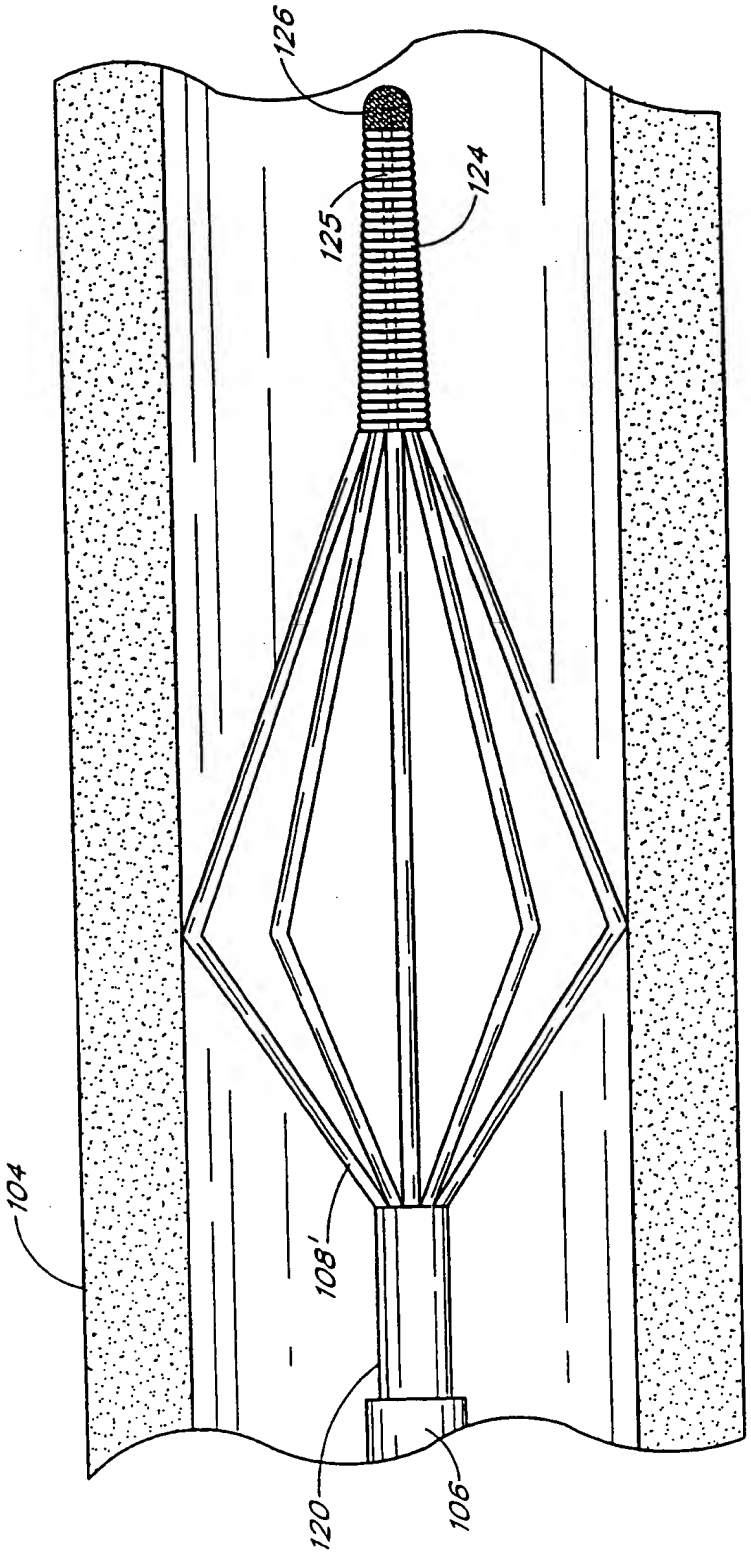

FIG. 1C

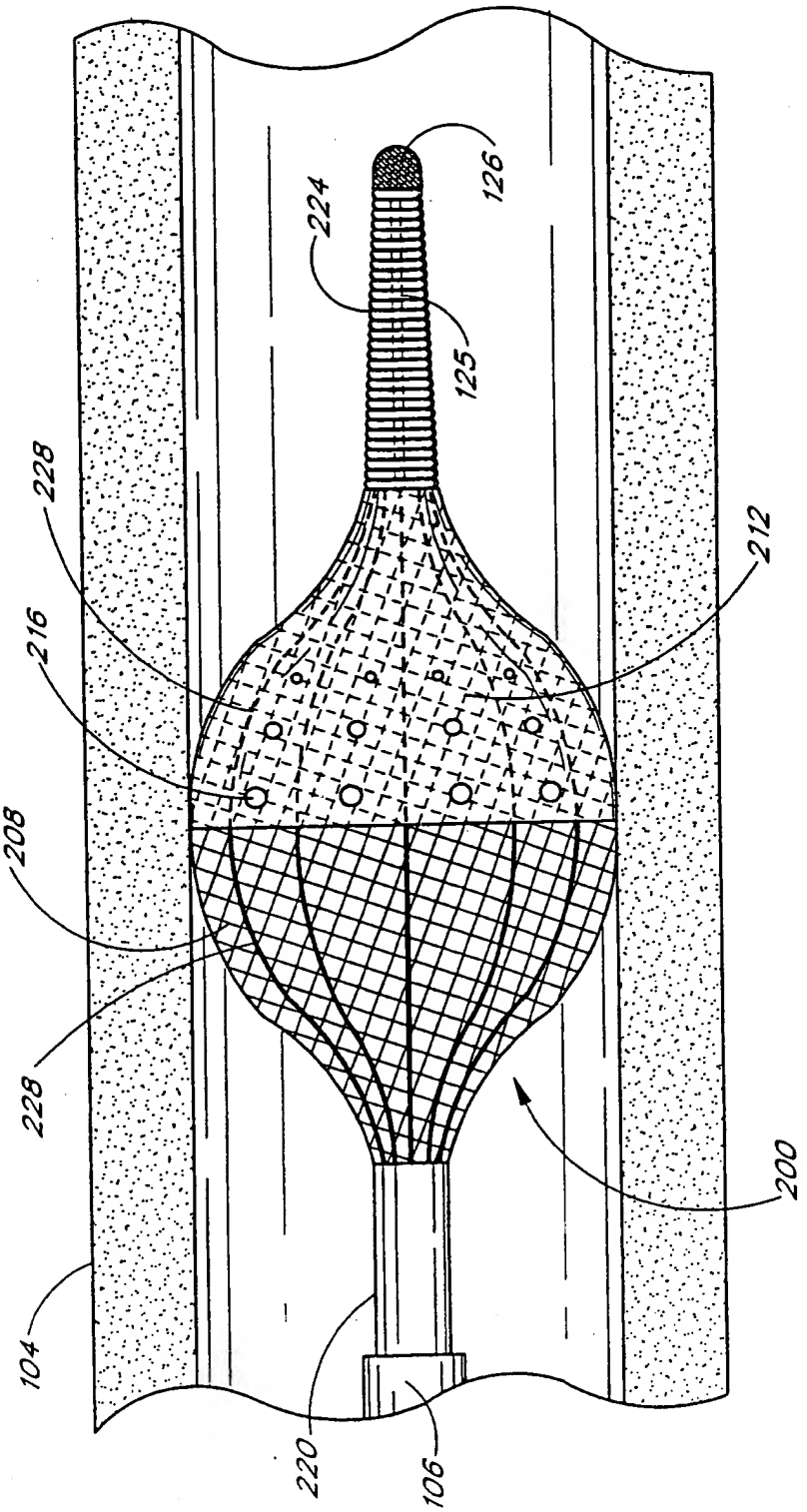

FIG. 2A

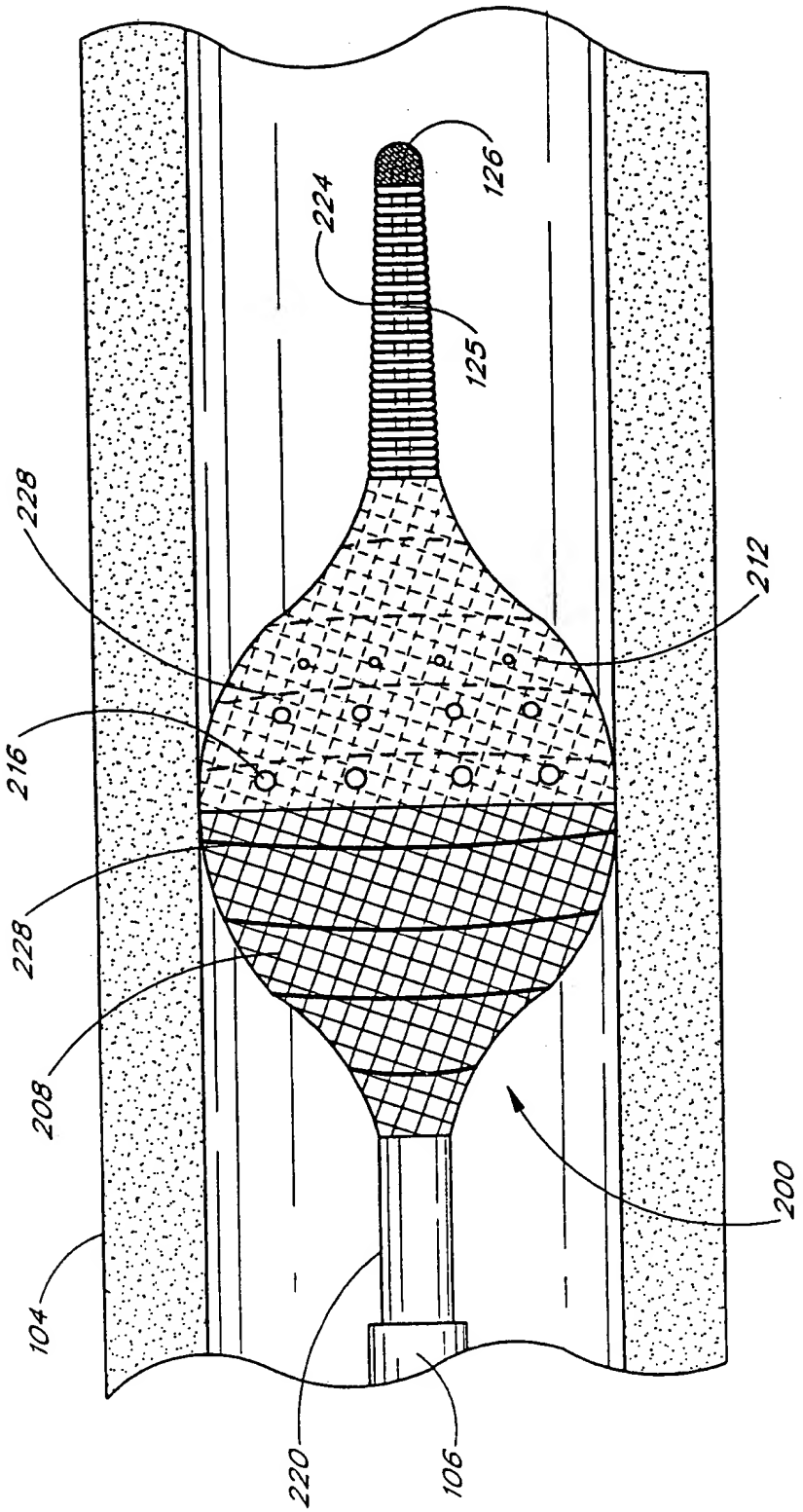

FIG. 2B

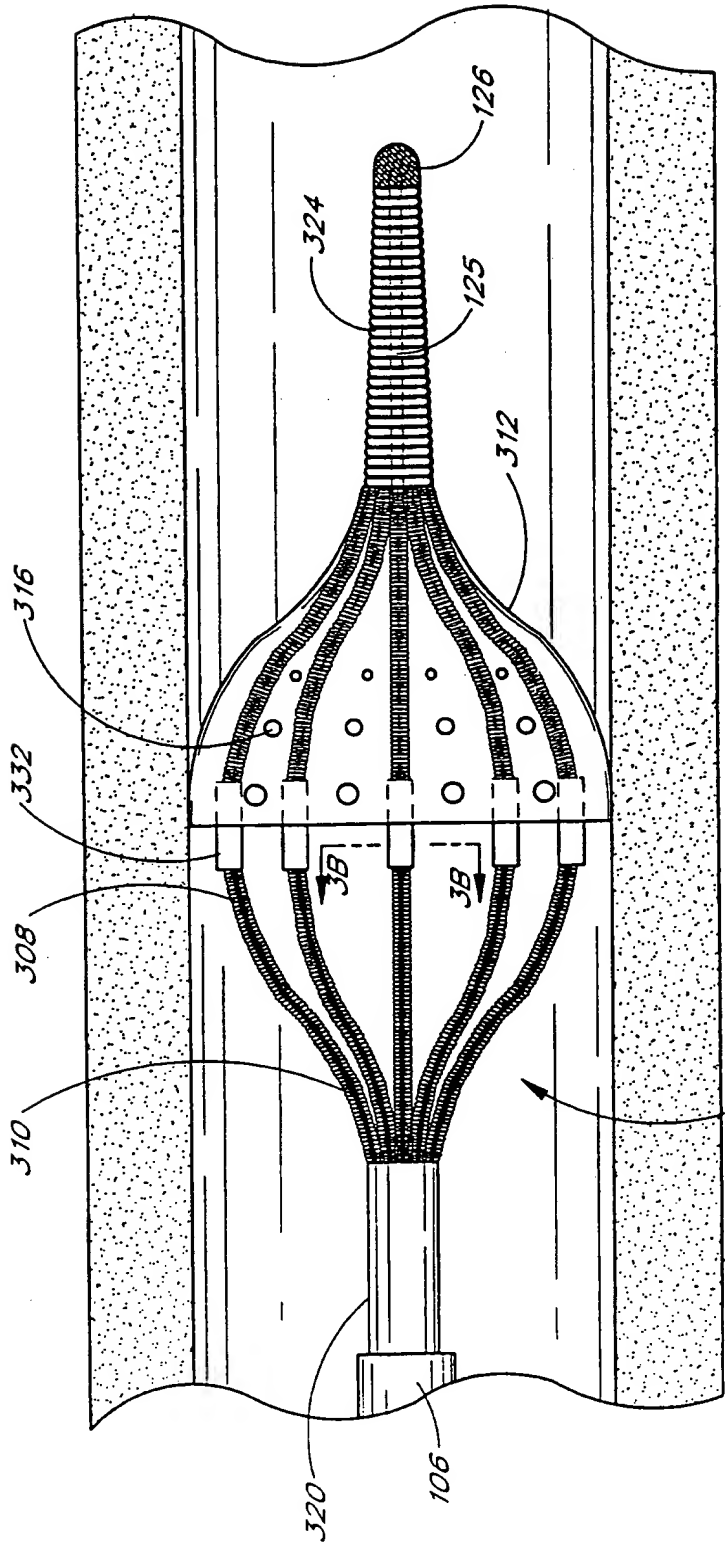
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FIG. 3A

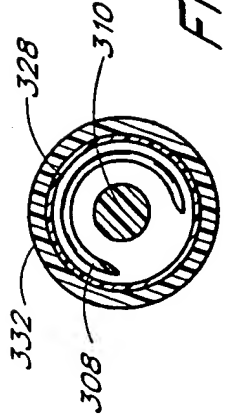
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FIG. 3B

FIG. 5A

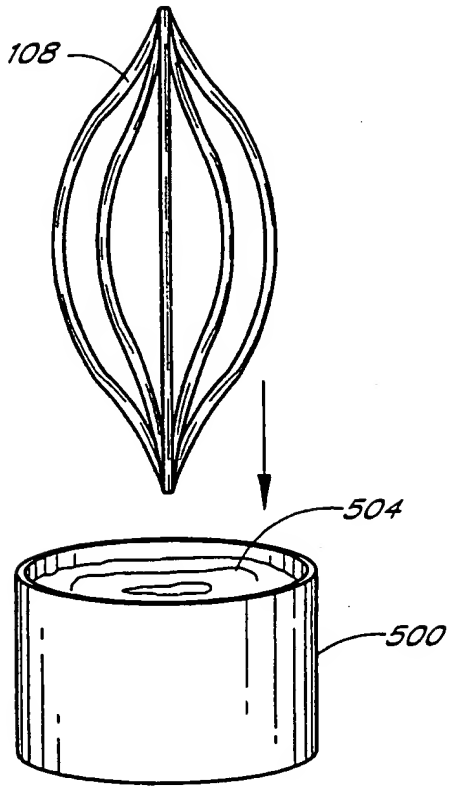
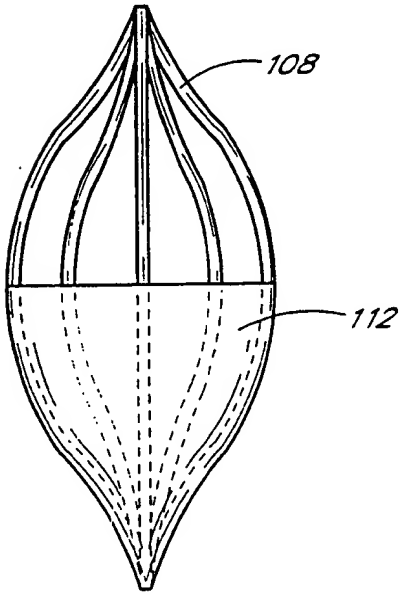


FIG. 5B



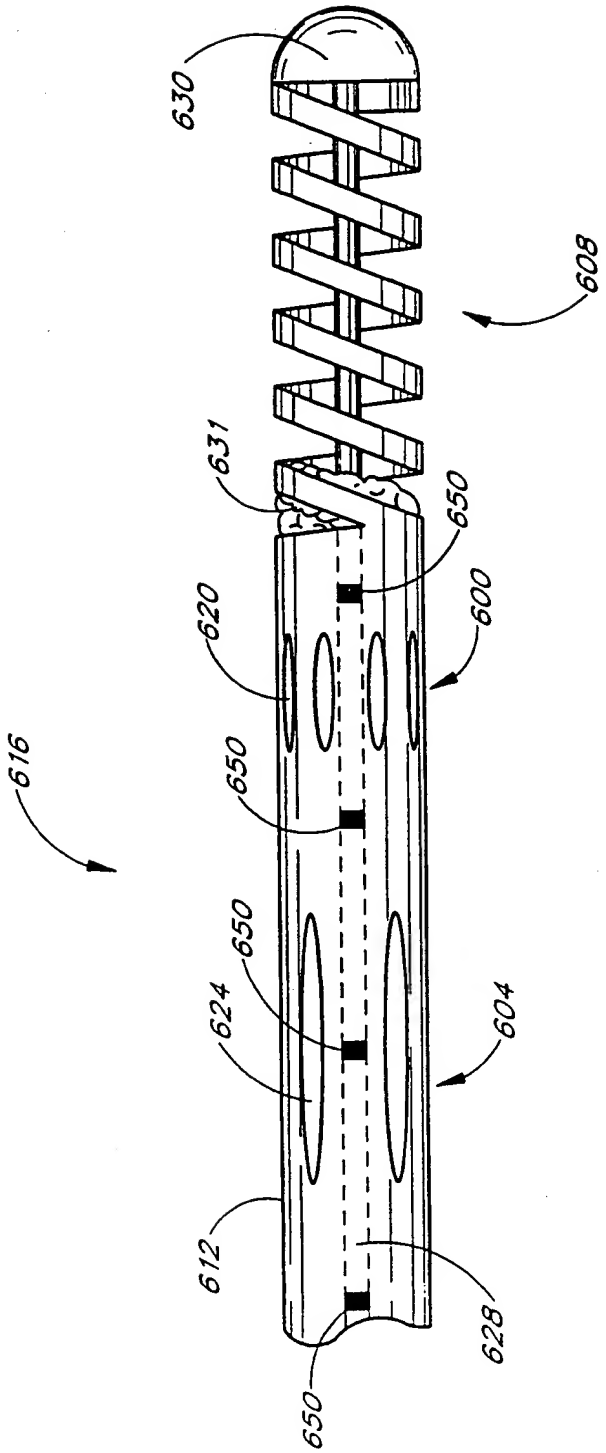


FIG. 6

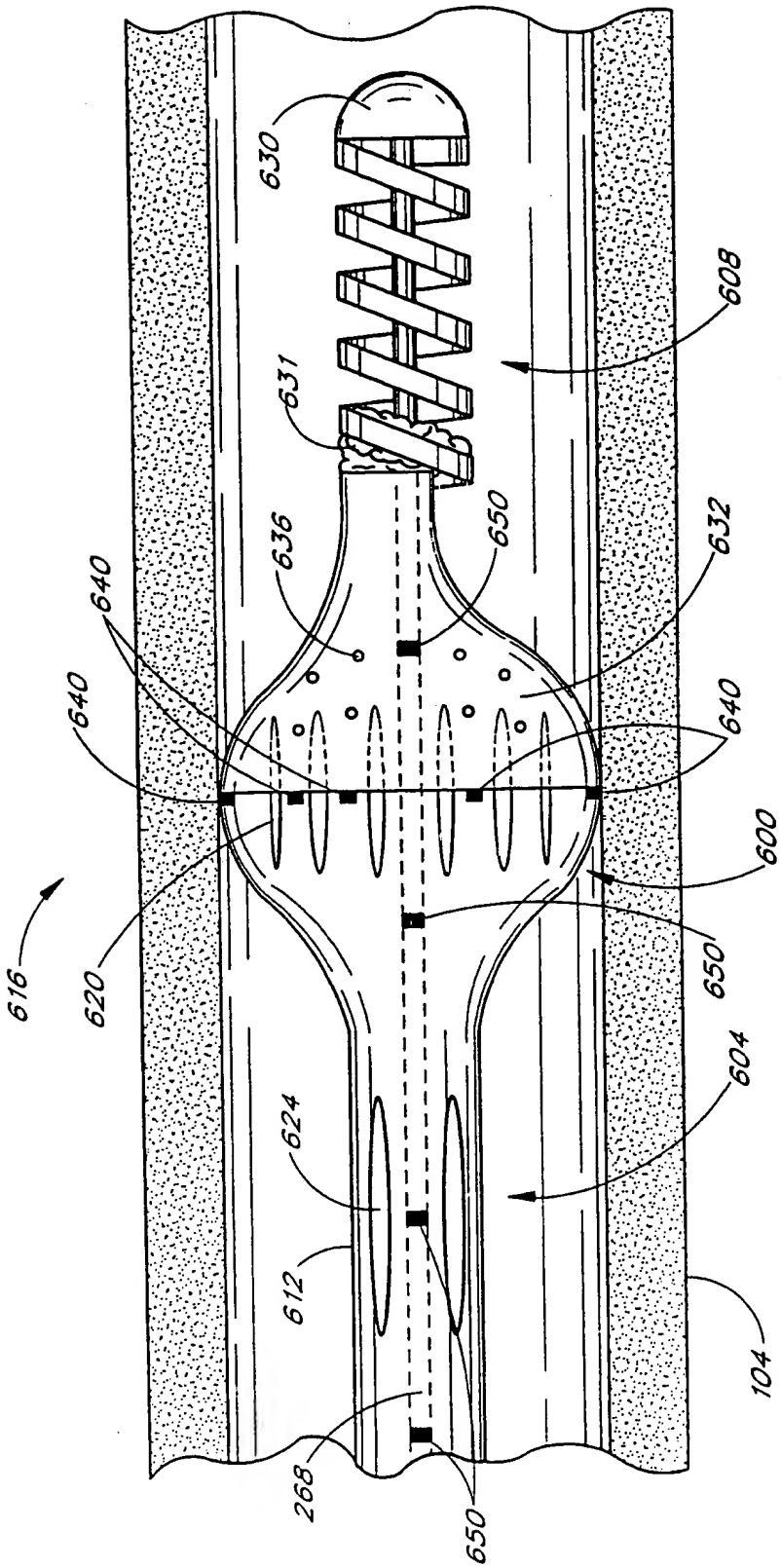

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FIG. 7

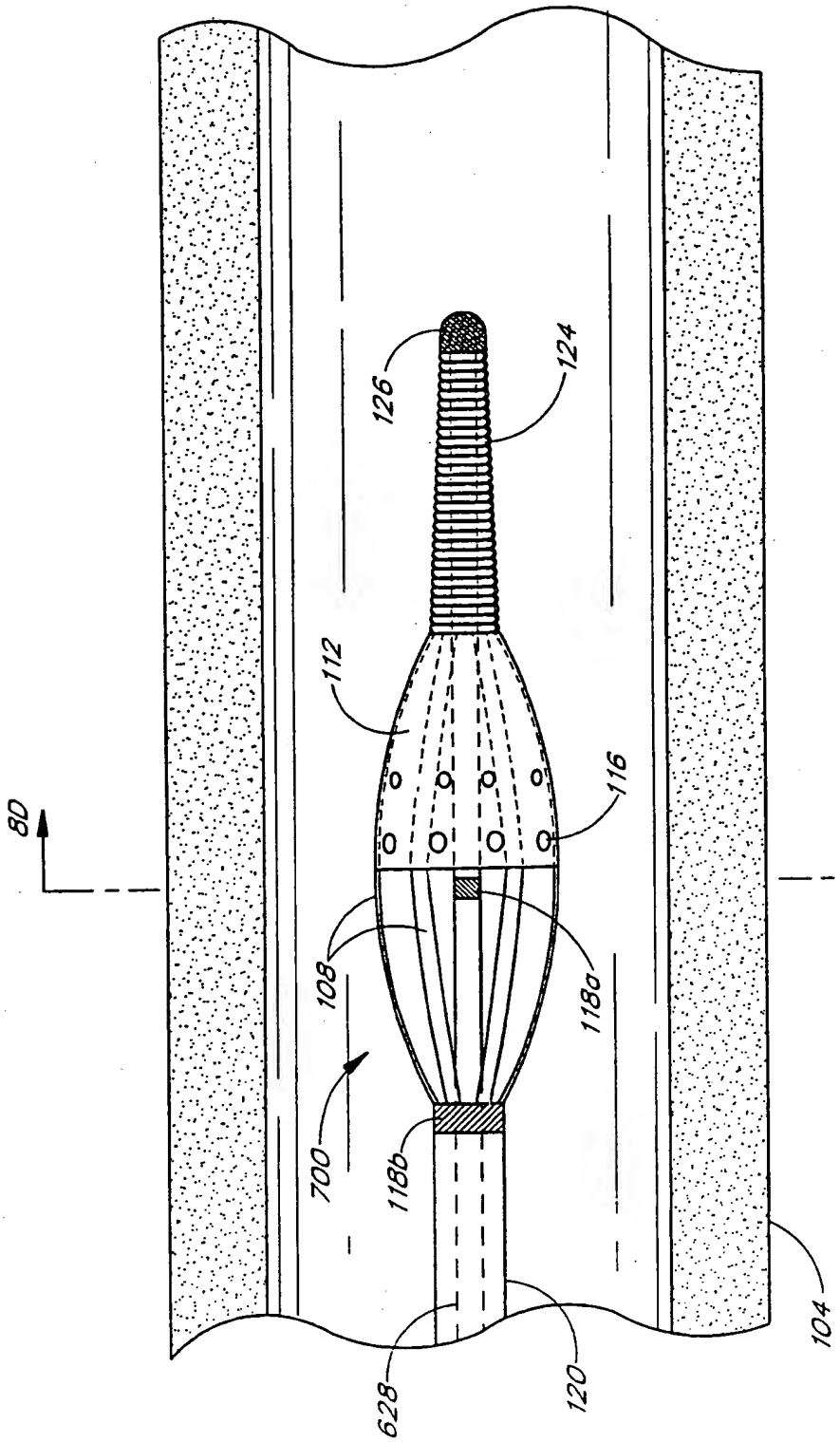

FIG. 8A

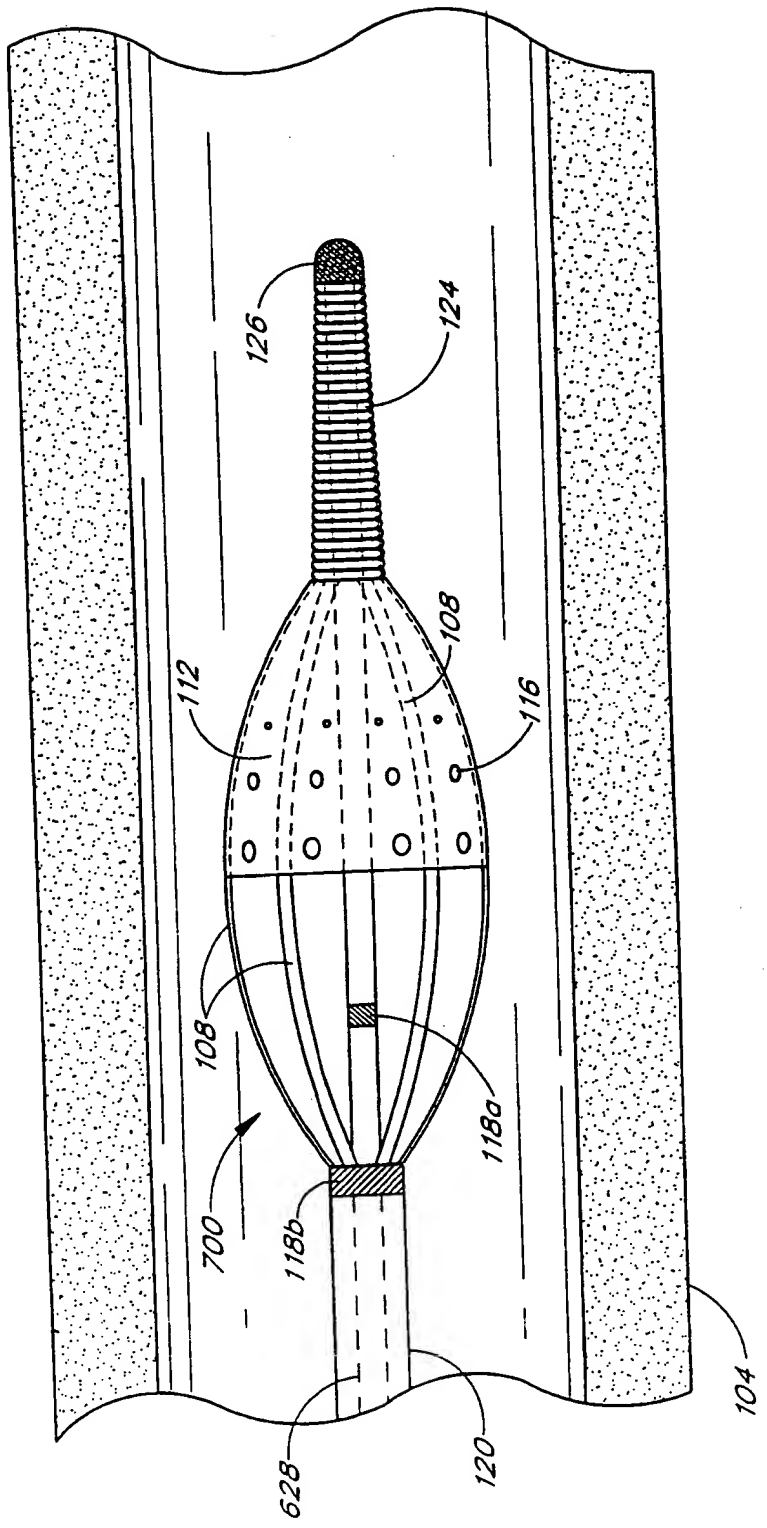

FIG. 8B

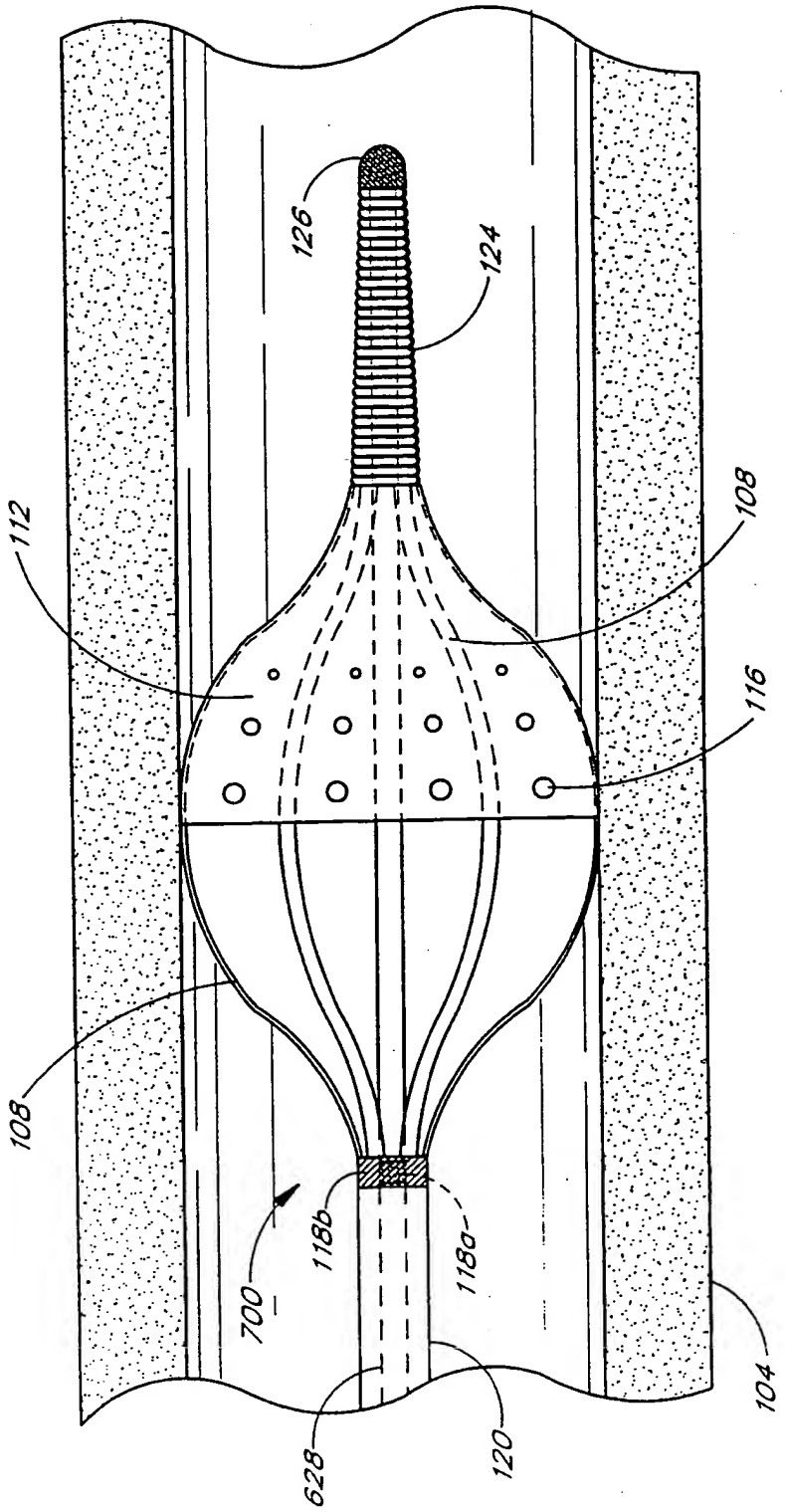

FIG. 8C

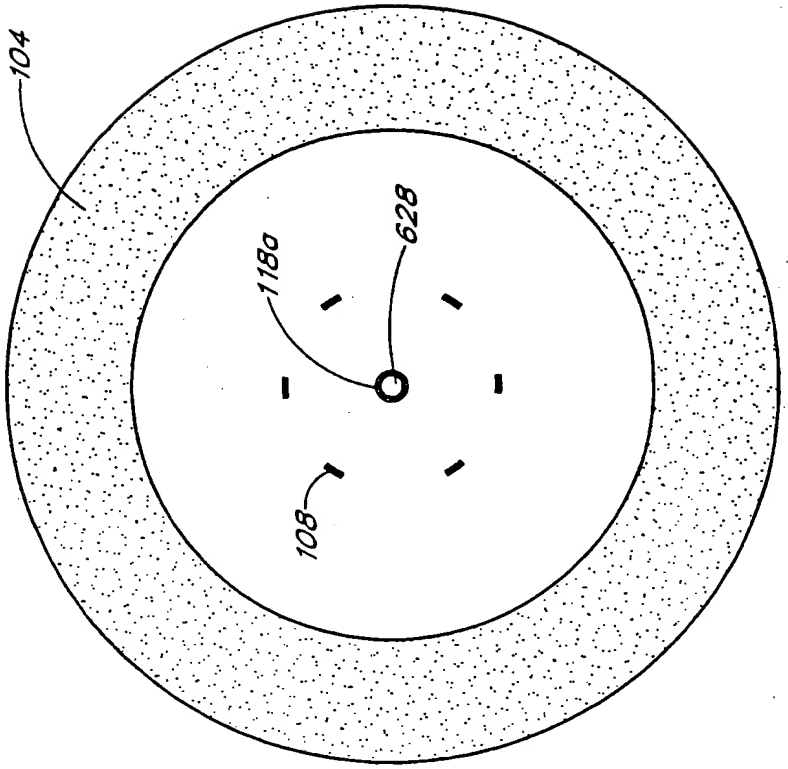

FIG. 8D

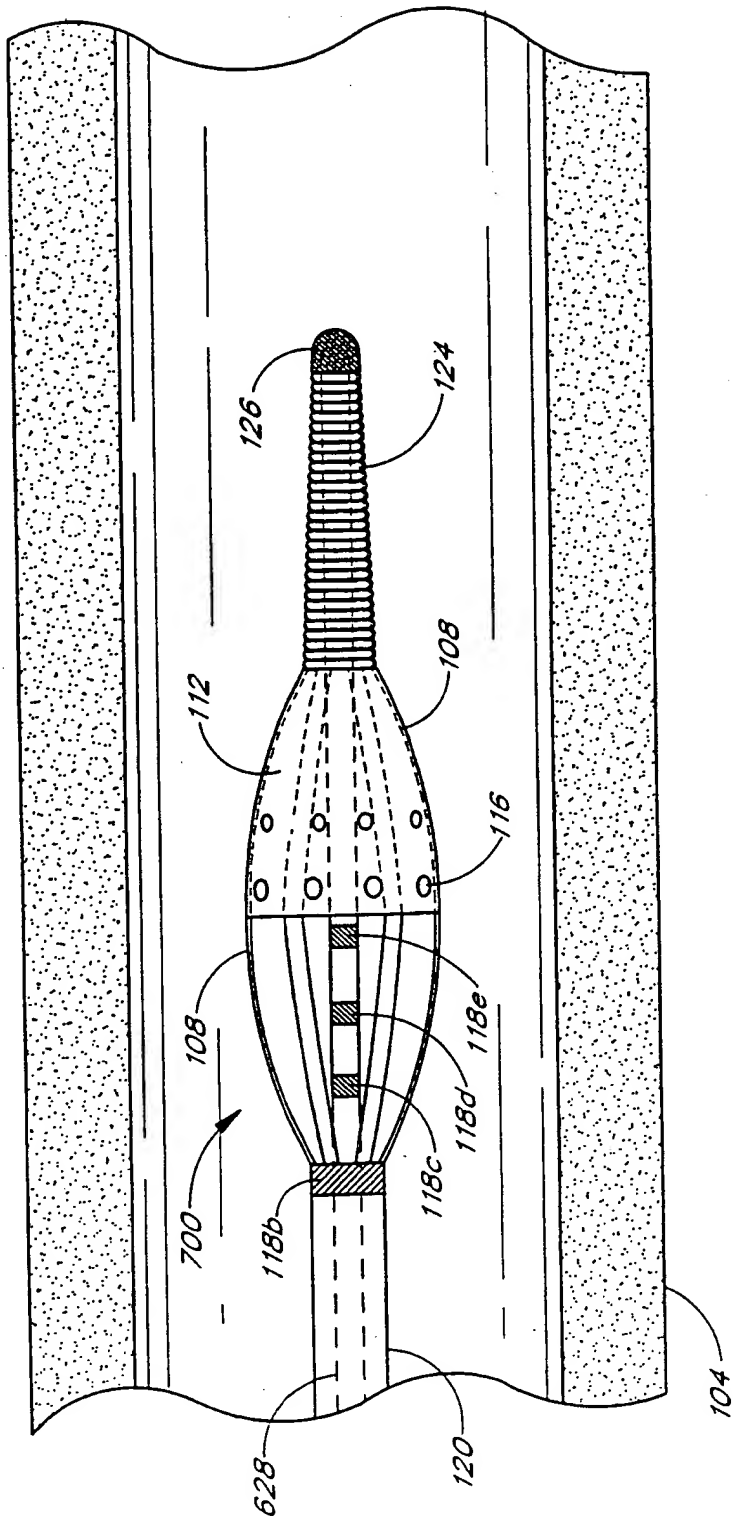

FIG. 9

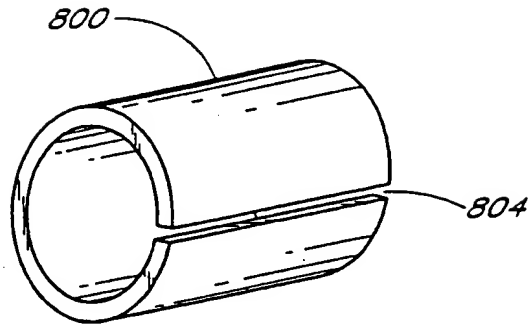

FIG. 10A

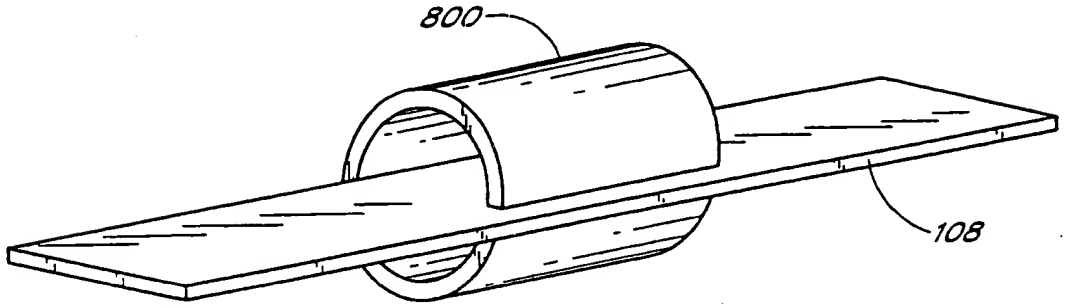

FIG. 10B

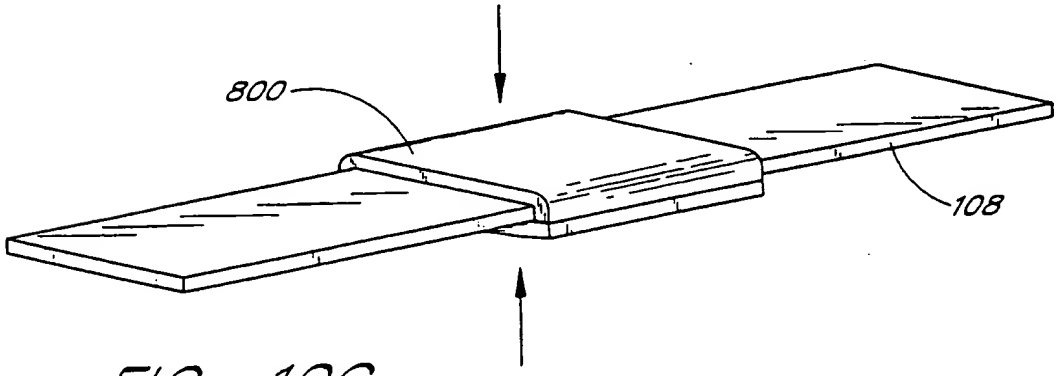

FIG. 10C

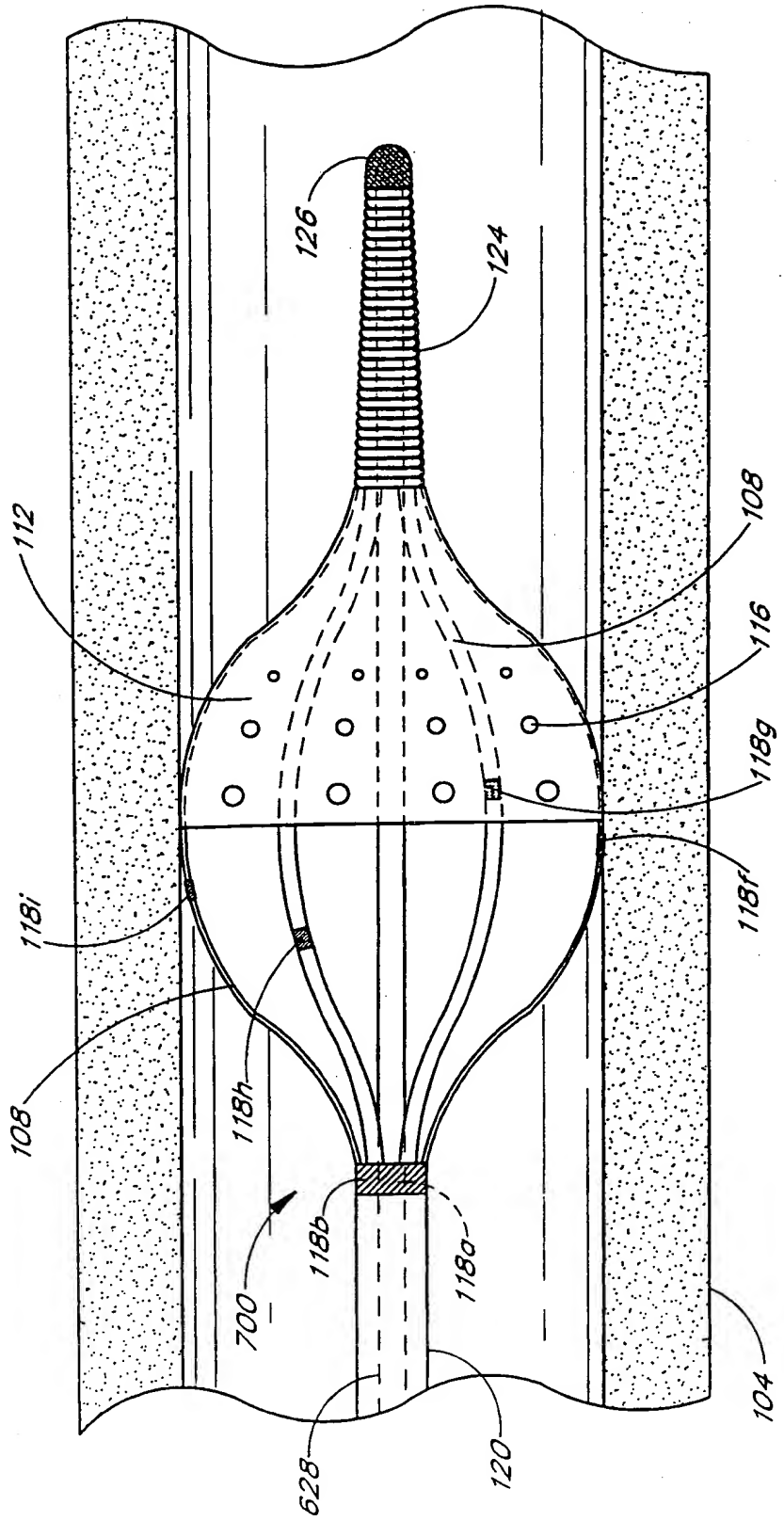
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FIG. 11

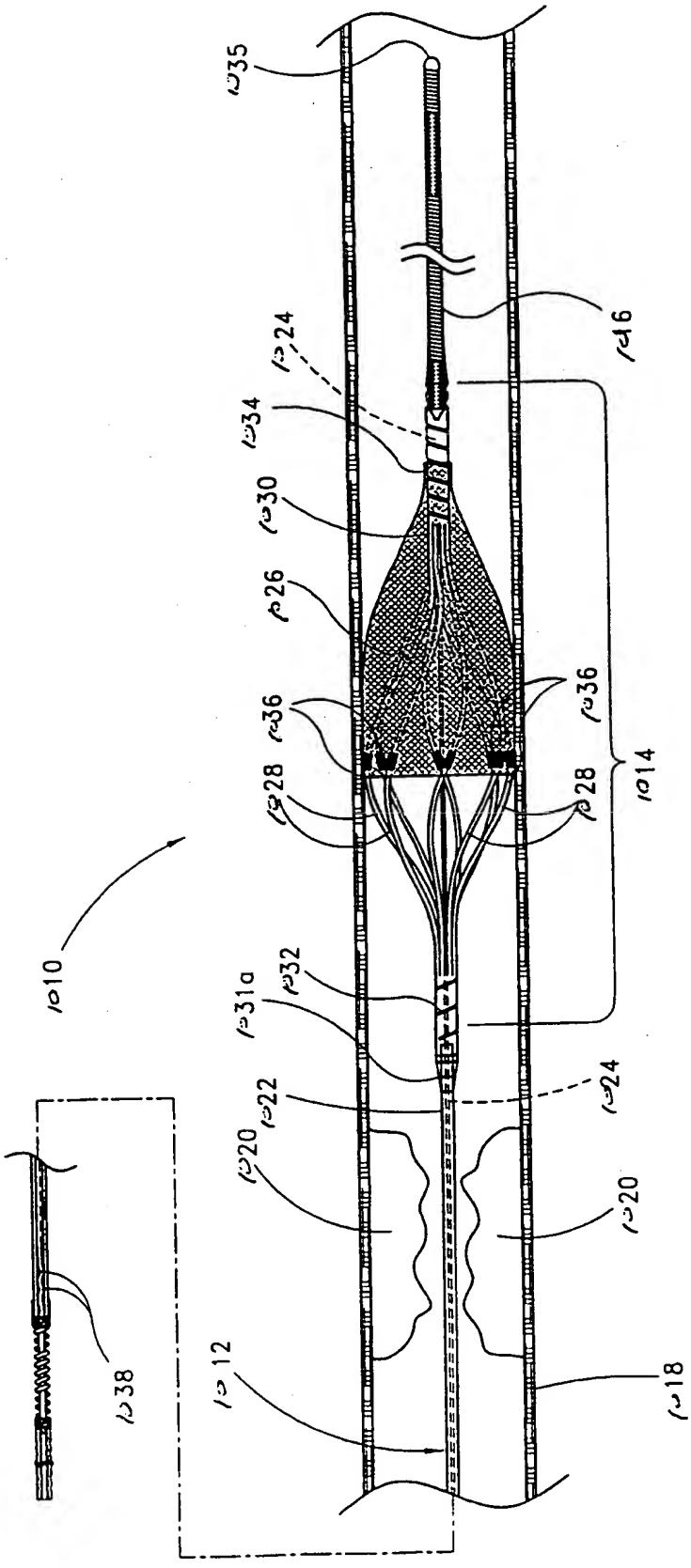

Fig. 12

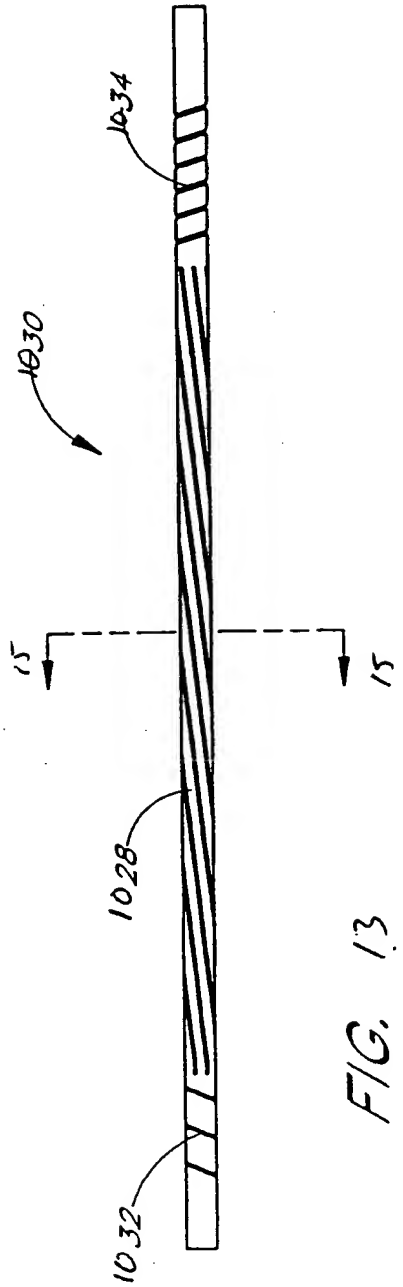

FIG. 13

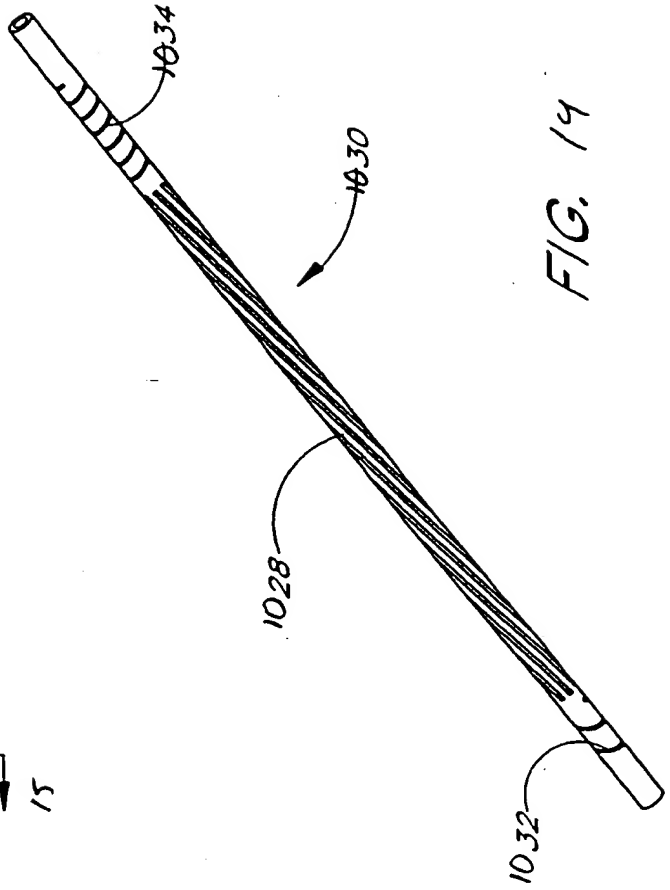

FIG. 14

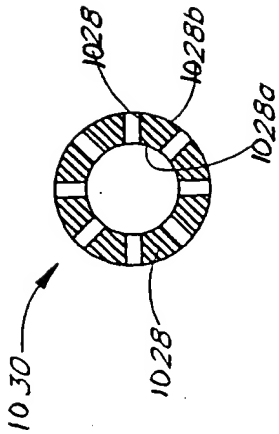

FIG. 15

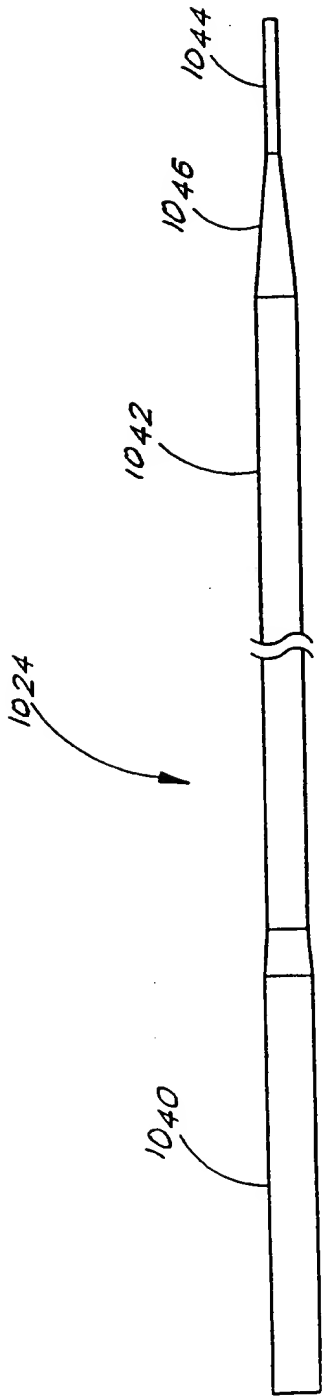

FIG. 16

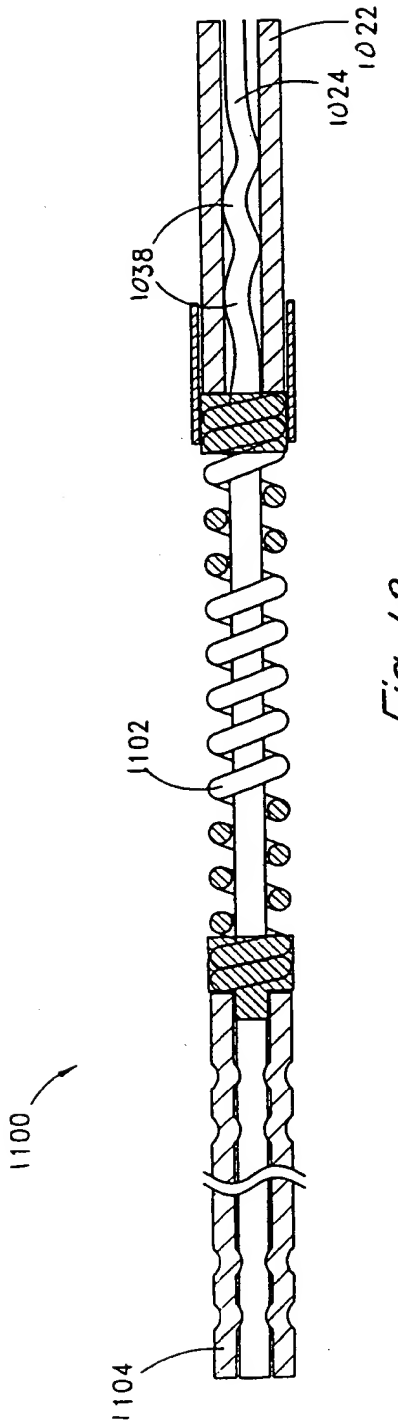

Fig. 18

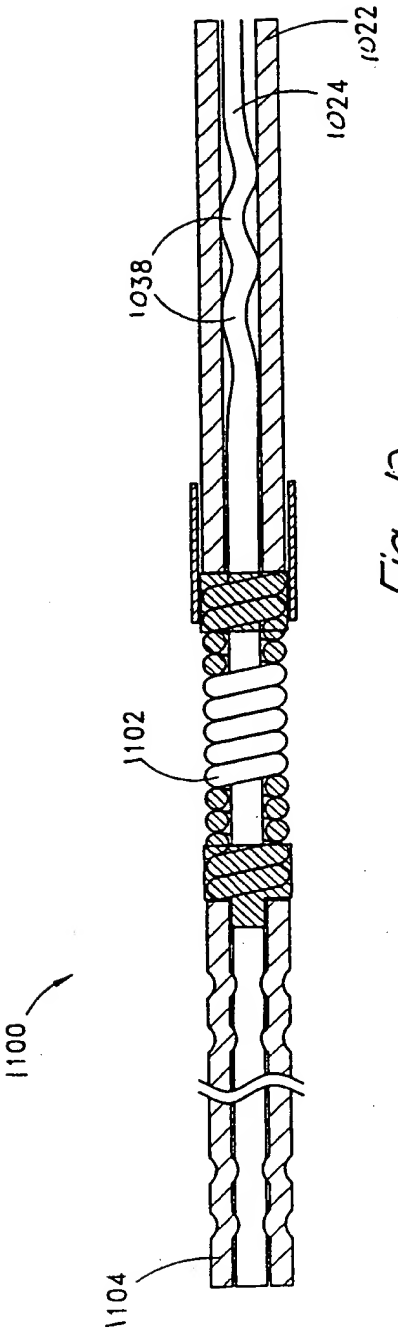

Fig. 17

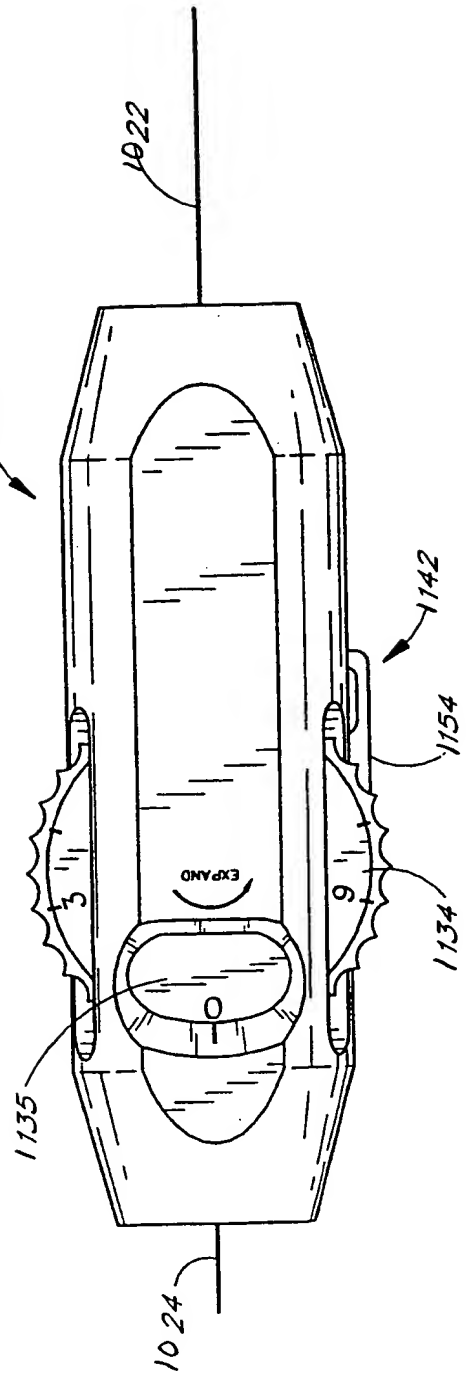

FIG. 19A

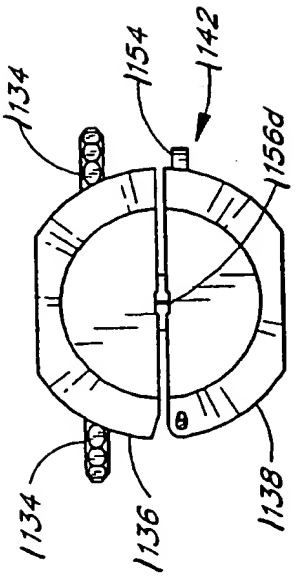

FIG. 19B

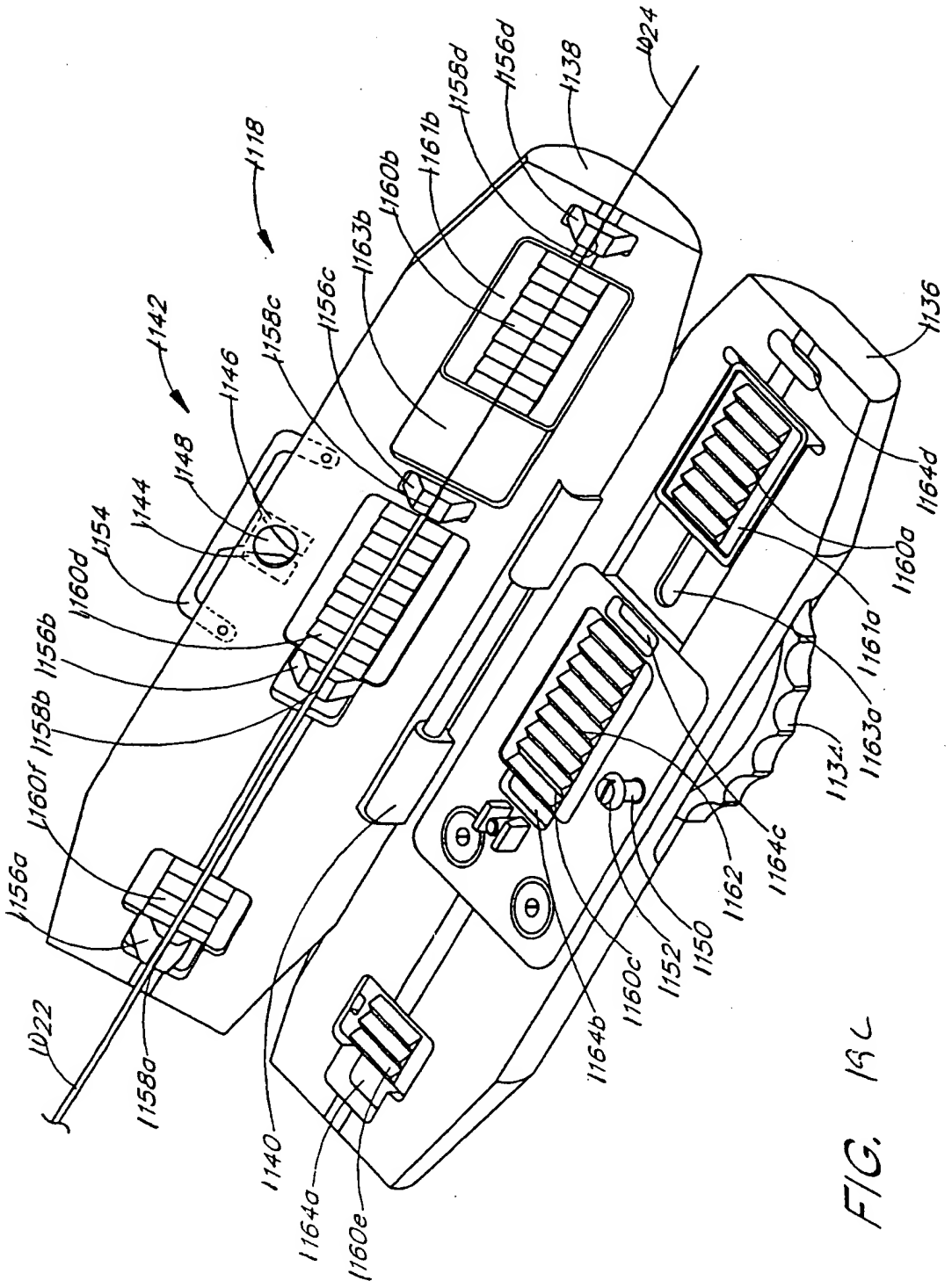
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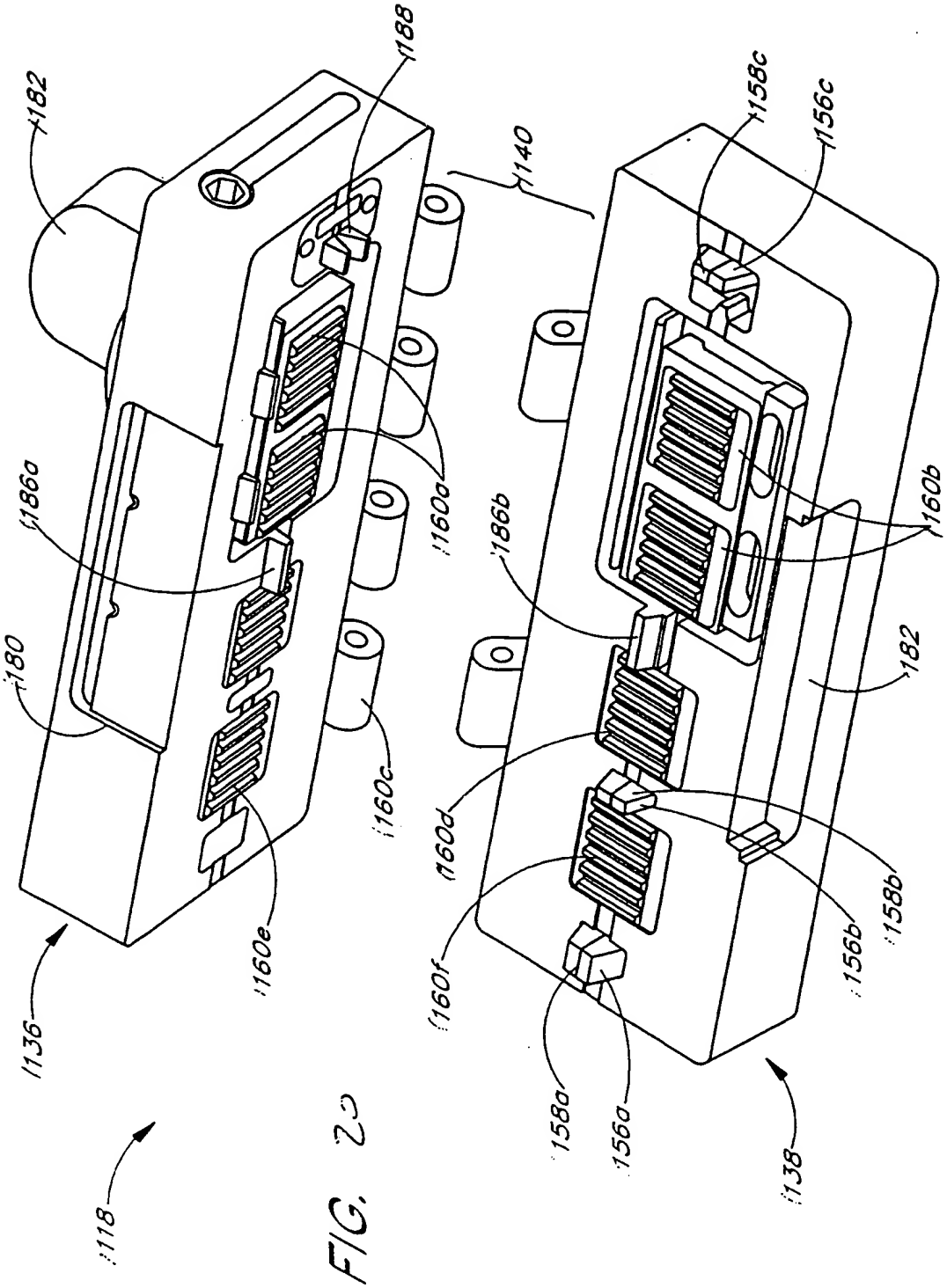
FIG. 19C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138

FIG. 23

INTERNATIONAL SEARCH REPORT

Internatic Application No
PCT/US 00/35159

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 44510 A (BIOGUIDE CONSULTING, INC.) 10 September 1999 (1999-09-10)	1-7,10, 11, 13-15, 18-20, 22-24,26
Y	the whole document	8,9,16, 17
A		27
Y	WO 99 16362 A (BOSTON SCIENTIFIC LIMITED) 8 April 1999 (1999-04-08) page 13, line 6 - line 13	8,9
Y	US 6 001 118 A (DANIEL ET AL) 14 December 1999 (1999-12-14) column 14, line 10 -column 21; figure 21A	16,17

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 May 2001	29/05/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatic Application No
PCT/US 00/35159

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 1061856 A	27-12-2000
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